

BEFORE THE IOWA BOARD OF PHARMACY

IN THE MATTER OF:)	CASE NO: 2012-52
)	DIA NOS. 12PHB029
Pharmacy License of)	
BAUDER PHARMACY, INC.)	
License No. 222)	
)	FINDINGS OF FACT,
Pharmacist License of)	CONCLUSIONS OF LAW,
MARK GRAZIANO)	DECISION AND ORDER
License No. 16752)	
)	
RESPONDENTS)	

On May 3, 2012, the Iowa Board of Pharmacy (Board):

- found probable cause to file Statements of Charges against Bauder Pharmacy, Inc. and Mark Graziano (Respondents);
- issued an Order of Immediate Suspension and Order to Show Cause that immediately suspended the controlled substances registration (number 1100280) issued to Bauder Pharmacy Inc.; and
- issued an Emergency Adjudicative Order indefinitely suspending the pharmacist license of Mark Graziano.

These documents were personally served on Respondents Bauder Pharmacy, Inc. and Mark Graziano on May 10, 2012. A June 26, 2012 hearing was initially scheduled on the Emergency Adjudicative Order and Statement of Charges issued to Mark Graziano. The hearing was continued four times at Respondents' request.

On October 8, 2012, the state filed Motions to Amend the Statements of Charges and First Amended Statements of Charges against both Respondents. Respondents did resist the Motions to Amend the Statements of Charges, and the motions were granted on November 30, 2012. Prehearing conferences were held on January 30 and February 22, 2013.

The consolidated hearing was held on February 26 and 27, 2013 in the Board Conference Room, 400 SW 8th Street, Des Moines, Iowa. The following members

of the Board served as presiding officers for the hearing: DeeAnn Wedemeyer Oleson, Vice-Chairperson; James Miller; Edward McKenna; and LaDonna Gratias. Assistant Attorney General Theresa O'Connell Weeg represented the state. Respondents Bauder Pharmacy and Mark Graziano were represented by attorney Rick Olson. The hearing was open to the public at Respondents' request, in accordance with Iowa Code section 272C.6(1) and 657 IAC 35.19(10). Administrative Law Judge Margaret LaMarche assisted the Board in conducting the hearing and was later instructed to prepare the Board's written Decision and Order, in conformance with their deliberations.

THE RECORD

The hearing record includes the testimony of Jean Rhodes, Sue Mears, Kirby Small, Lloyd Jessen, Jennifer Higgins, and Mark Graziano. The record also includes State Exhibits 1-77 and 79 and Respondent Exhibits D-N. A Protective Order was issued for all exhibits containing patient names, with the exceptions of Respondents' Exhibits L and M. The record also includes the following procedural motions and orders: Board Orders Granting Motions to Continue; Order Following Prehearing Conference; State and Respondent Witness and Exhibits Lists; State Motion to Strike Lloyd Jessen from Respondent's Witness List, Respondent Resistance, and Order Denying State's Request to Strike; Respondent's Objections to State Exhibits and Order Overruling Respondent's Objections; State Motion for Protective Order and Order Granting Protective Order; and State's Hearing Brief.

FINDINGS OF FACT

Licensure/Ownership/Staffing of Bauder Pharmacy

1. At all times material to this Decision and Order, Bauder Pharmacy, Inc. operated a licensed general pharmacy (license number 222) located at 3802 Ingersoll Avenue in Des Moines, Iowa. At all times material to this Decision and Order, Mark Graziano, R.Ph. was both the majority owner and the pharmacist in charge of Bauder Pharmacy. Mr. Graziano has been licensed to practice pharmacy (license number 16752) in the state of Iowa since 1986. (Jean Rhodes testimony; State Exhibits 1, 3, 5, 7)
2. Bauder Pharmacy is a small, independently owned retail pharmacy that also has a lunch counter and soda fountain. Mark Graziano owns 68% of Bauder

Pharmacy; his sister, Kim Robertson, owns 20%; and his mother owns the remaining 12%. Kim Robertson is also an Iowa licensed pharmacist and was working full-time at Bauder Pharmacy at all times relevant to the Statements of Charges. Bauder Pharmacy also had the following employees:

- Jay Wangerin, R.Ph., who was working as a part-time pharmacist (approximately 12 hours a week);
- Jennifer Higgins, who was working as a full-time pharmacy technician (45 hours a week);
- Jolene Cavanaugh, who worked at the lunch counter, ordered over-the-counter products for the store, and handled customer billing; and
- Shannon McGuire, who worked in the soda fountain.

(Rhodes, Graziano, Higgins testimony; State Exhibits 11, 29-34)

Anonymous Complaint Re: Illegal Distribution of Hydrocodone

3. On September 28, 2011, the Board received an anonymous telephone complaint from a person who claimed that Mark Graziano was illegally distributing 5,000 to 10,000 hydrocodone pills a month from Bauder Pharmacy. According to the anonymous complainant, Mark Graziano handed the hydrocodone bottles out the back door of the pharmacy to an individual who distributed them. The complainant stated that he was willing to submit a complaint form but hoped to remain anonymous because Mark Graziano had threatened him with “guys from out of state” if he spilled the beans. The complainant also claimed that Mark Graziano had him hooked on hydrocodone, but that he was now trying to get clean. (State Exhibit 8) The Board did not hear from the complainant again until May 11, 2012. (State Exhibit 35)

Shopper Surveys of Bauder Pharmacy

4. In March 2012, inspectors from the National Association of Boards of Pharmacy conducted two “shopper surveys” at Bauder Pharmacy. Both inspectors presented themselves to the pharmacy as new customers with new prescriptions. Both inspectors completed an Iowa Pharmacy Shopper Survey Reporting Form that describe a number of deficiencies in their “shopper” experience. (Rhodes testimony; State Exhibits 7, 9, 10)

a. There were two pharmacists on duty during the March 8, 2012 shopper survey conducted by inspector Cheryl Anderson, R.Ph. Ms. Anderson only had contact with one of the pharmacists, who she was later able to identify as Mark Graziano. Ms. Anderson initially gave her prescription to a female employee who was not wearing a name tag. The employee did not ask Ms. Anderson for any of her health history, current health conditions, medications, or allergies. Mr. Graziano asked Anderson for her date of birth and address. In her report, Ms. Anderson notes that Mr. Graziano appeared more focused on a man who had entered the pharmacy while her prescription was being filled. The man did not stop at the drop-off or pick-up counter but walked directly to the rear of the pharmacy.

Ms. Anderson's prescription was ready in less than 10 minutes. The female employee took Anderson's payment and asked Mr. Graziano if Anderson needed to know anything. Mr. Graziano told the employee "take in AM." When the employee looked puzzled, Mr. Graziano said "Cheryl, take in AM" and then walked to the rear of the pharmacy. Ms. Anderson was not provided any counseling literature or monograph with the prescription. Mr. Graziano did not counsel Ms. Anderson on any of the medication's possible side effects, which included increased urination, decrease in blood pressure, and dizziness. The prescription given to Anderson was mislabeled. The label read: "Triamterene-HCTZ 37.5-2#15, but the drug strength for the HCTZ was 25 mg not 2 mg. In addition, the prescription bottle had an easy open lid that was not requested or authorized by Ms. Anderson. (State Exhibit 9)

b. A female in a white lab coat waited on secret shopper Denise Frank at the time of the March 14, 2012 survey. The female employee was not wearing a name tag and did not identify herself to Ms. Frank as a pharmacist. The employee asked Ms. Frank about allergies but did not ask about her disease states or any other medications that she was taking. Ms. Frank noted in her report that it would have been prudent of the pharmacist to ask her about her OTC medications in order to prevent duplicate therapy because the prescription medication was also available over-the-counter.

Ms. Frank also noted that there were no privacy panels for the counseling area. A customer was standing directly behind her while the female waited on her and customers at the fountain counter could hear everything being said. The prescription was ready in eight minutes, and the female employee spoke to Ms. Frank as she rang up the order. The employee told Frank to avoid caffeine and

spicy foods and added “it’s 1 twice a day.” The prescription was put in a non-child proof container that Ms. Frank did not request. (State Exhibit 10)

March 16, 2012 Pharmacy Inspection

5. Jean Rhodes, R.Ph. has been a pharmacist for 14 years and has been employed by the Board as a Compliance Officer for 8½ years. On March 16, 2012, Ms. Rhodes was assigned to conduct a pharmacy inspection of Bauder Pharmacy and to prepare an inspection report. This inspection was prompted by the anonymous complaint and by the results of the shopper surveys. Ms. Rhodes was assisted by Sue Mears, R.Ph., who was a new compliance officer in training. (Rhodes, Mears testimony)

Bauder Pharmacy’s last inspection had been conducted on July 24, 2008.¹ Ms. Rhodes explained the time gap between the two inspections. There is a backlog of routine pharmacy inspections, and the four year gap between inspections at Bauder Pharmacy is not that unusual. Some pharmacies have not had an inspection in 5 or 6 years. The Board’s Compliance Officers are assigned to specific territories, and they give first priority to complaint investigations. If there is a need for a complaint investigation, the Compliance Officer will usually conduct a routine inspection at the same time. (Rhodes testimony; State Exhibits 7, 11; Respondent Exhibit N)

a. The Pharmacy Inspection Report was issued by Jean Rhodes on March 22, 2012. The report notes that Bauder Pharmacy maintains the following hours: Monday-Friday 8:30-6:00, Saturdays 9:00-3:00, Sundays 10:00-12:00, and Holidays, 10:00-12:00. The retail store and lunch counter are only open when the pharmacy is also open because the pharmacy dispensing area cannot be separately locked. At the time of the March 16th inspection, the pharmacy was performing sterile compounding of two medications (Lupron and HCG). The counseling area was limited. The pharmacy specialized in fertility medications, and fertility counseling was encouraged before and after business hours to promote confidentiality. (State Exhibit 11, pp. 57-58)²

¹ The July 2008 inspection included an audit of Schedule II controlled substances but did not include an audit of Schedule III or IV controlled substances. The inspection report only included a count of the Schedule III and IV inventory on hand. A total of 3000 tablets of all dosages of hydrocodone APAP were on hand in the pharmacy at the time of the 2008 audit. (Respondent Exhibit N)

² The page numbers provided in the Decision and Order refer to the consecutive pagination throughout the state’s exhibit book which is found in the lower right hand corner of each page.

b. During the March 16th inspection, the Board's Compliance Officers reviewed the pharmacy's Schedule II Controlled Substance Perpetual Inventory, its annual inventory (last performed May 3, 2011), and hard-copies of prescriptions, invoices, and executed DEA 222 forms. The Compliance Officers did not perform a controlled substances audit during the March 16th inspection. (State Exhibit 11, pp. 57-58)

c. The Inspection Report describes the following areas of non-compliance requiring correction:

- **Registration renewal.** Pharmacy technician Jennifer Higgins' registration had expired on September 30, 2010 and had not been renewed. See 657 IAC 3.11(2). Ms. Higgins submitted her renewal application to the Board on March 20, 2012.
- **Pharmacist in charge.** The pharmacy had minimal policies and procedures, which are the responsibility of the pharmacist in charge. See 657 IAC 6.2(14). The Compliance Officers provided pharmacist Kim Robertson with a guideline handout for policies and procedures.
- **Security.** Outdated medications, including controlled substances, and patient records were not effectively secured against theft, diversion or unauthorized access. See 657 IAC 6.7, 657 IAC chapter 21. Outdated medications and patient records were stored in the basement, which could be accessed by any store personnel or by delivery drivers because the back door is adjacent to the basement stairs. This was the second notice concerning the pharmacy's storage of outdated drugs, and Mark Graziano was told to contact his reverse distributor for disposal of the drugs.
- **Identification badge.** Although visible name badges are required for pharmacists by Board rule, Pharmacist Mark Graziano admitted that he seldom wears a name badge because his customers all know him. This was the second notice on this violation. See 657 IAC 8.4(4).
- **Drug supplier invoices.** The pharmacy's controlled substance invoices needed to be signed and dated when received by the pharmacist or other responsible individual. 657 IAC 6.9(1).
- **Training and utilization of pharmacy technicians and pharmacy support.** The pharmacy did not have a written policy for training of pharmacy technicians and pharmacy support persons and did not document training. See 657 IAC 8.14.

- ***Continuous quality improvement program(CQI).*** The pharmacy did not have the required written CQI program, which is required to be an ongoing, systematic program of standards and procedures to detect, identify, evaluate and prevent medication errors. Pharmacists Mark Graziano and Kim Robertson were able to explain their processes for a dispensing error. Mr. Graziano estimated that the pharmacy had about one error a week, while Ms. Robertson thought errors rarely happened. See 657 IAC 8.26.
- ***Schedule II prescriptions.*** RX 673021 was written for Oxy 20mg/ml, 10 ml, but the manufacturer supplies a 30ml container. The pharmacy had dispensed a 30ml container without documenting that the pharmacist contacted the prescriber for authorization to change the prescribed quantity. See 657 IAC 10.21(5).
- ***Schedule II prescriptions-partial filling.*** If the pharmacist is unable to supply the full quantity of Schedule II controlled substance prescription, the pharmacist may partially fill the prescription and make a notation on the record as long as the remaining portion of the prescription is filled within 72 hours. If the remaining portion of the prescription can't be filled within the 72 hours then the prescriber must be notified and a new prescription must be obtained. The pharmacy was partially filling Schedule II prescriptions and supplying the balance of the prescription beyond the 72 hour limit, resulting in several negative balances on the Schedule II perpetual log. See 657 IAC 10.23.
- ***Information included.*** The perpetual inventory record shall identify all receipts and disbursements of Schedule II controlled substances by drug or by national drug code number. The record shall be updated to identify each prescription filled and each shipment received. The pharmacy had multiple negative balances in the Schedule II perpetual inventory. See 657 IAC 10.33(2).
- ***Schedule I and II records.*** Inventories and records of controlled substances listed on Schedule I and II must be maintained separately from all other records. The pharmacy kept its Schedule II invoices with its Schedule III-V invoices. See 657 IAC 10.34(1).
- ***Ordering or distributing Schedule I or II controlled substances-electronic ordering system.*** When a pharmacy receives a shipment of Schedule I or II drugs, it is required to create a record of the quantity of each item and the date received and then electronically link it to the original order and identify the individual reconciling the order. The pharmacy had never electronically linked the receipt of Schedule I and II drugs for a

wholesaler. During the inspection, Mr. Graziano called the wholesaler's help line and was instructed on the procedure. See 657 IAC 10.34(7).

- ***Record and procedure.*** Each inventory shall contain a complete and accurate record of all controlled substances on hand at the date and time inventory is taken. The pharmacy's annual inventory on 5/3/11 had no value for hydrocodone/APAP 2.5/500mg. If there is no drug, the entry should have been zero. Pharmacist Robertson believed they had copied the drug list from the previous year but had no 2.5/500 mg on hand as it is seldom used. See 657 IAC 10.35(1).
- ***Newly controlled substances.*** Carisoprodol became a Schedule IV drug on 1/12/12 but had not been inventoried as required by Board rule. See 657 IAC 10.35(8).
- ***Sterile compounding.*** Mark Graziano was the only pharmacist who prepared sterile compounded products. The following deficiencies were noted with respect to sterile compounding:
 - ✓ The pharmacy had a hood that was inspected yearly rather than every 6 months as required;
 - ✓ The pharmacy lacked a written quality assurance (QA) procedure and lacked written policies and procedures for sterile compounding. 657 IAC 13.3(2), 13.6, 13.31;
 - ✓ The pharmacy lacked documentation of the training and proficiency of its personnel involved with sterile compounding. 657 IAC 13.3(3);
 - ✓ The refrigerator had two unlabeled vials of HCG injectable. There were no batch records and no labeling of the product. 657 IAC 13.7(2);
 - ✓ Lupron injections were assigned a 30 day beyond-use date but are only permitted to have a 14 day beyond use date. 657 IAC 13.7(11);
 - ✓ Media fill testing was required annually but had never been done. 657 IAC 13.25;
 - ✓ There was peeling paint and areas that needed caulking in the buffer area where the primary engineering control device was located. 657 IAC 13.27(2);
 - ✓ There was no written cleaning procedures and no documentation of cleaning. 657 IAC 13.28;
 - ✓ All cleanrooms, laminar airflow workbenches, and barrier isolators are required to be certified every six months or whenever the device or room is relocated or altered or whenever major service to the facility is performed. Certification had only been done annually. 657 IAC 13.29.

- ✓ Microbial sampling had never been done, there were no pressure differential monitors, and there were no procedures concerning environmental requirements. 657 IAC 13.29.
- **Verification of controlled substance refills.** The pharmacy had not verified controlled substance refills through a daily printout or logbook for the prior two years. Mark Graziano mistakenly believed that the Patient Monitoring Program (PMP) fulfilled this requirement. 657 IAC 21.25.
- **Patient med paks.** The pharmacy was preparing med paks for four customers with no labeling or recordkeeping for the med paks. Pharmacist Kim Robertson stated that she planned to discontinue providing med paks. 657 IAC 22.5.
- **Poison Prevention Packaging Act of 1970(PPPA), 15 U.S.C. §§ 1471-1476.** This Act requires pharmacies to dispense oral prescription drugs in special packaging unless the drug is exempt or the patient or prescribing practitioner requests nonspecial packaging. The majority of prescriptions were filled at Bauder Pharmacy using snap caps/easy off caps without documentation that the customer requested them. Pharmacist Robertson planned to contact customers to obtain signatures from those who want easy off caps. In addition, some of the pharmacy's customers brought in empty prescription vials for re-use, which also violates PPPA. Pharmacist Robertson agreed to stop this practice.

Bauder Pharmacy was required to correct these deficiencies and acknowledge the corrections to the Compliance Officer within 30 days of receipt of the inspection report. (Rhodes testimony; State Exhibit 11)

6. On April 12, 2012, Jean Rhodes met with Mark Graziano at the Board office to review Bauder Pharmacy's deficiency corrections. Although this type of review is usually conducted at the pharmacy, Mr. Graziano specifically asked to meet Ms. Rhodes at the Board's office. Ms. Rhodes made handwritten notes of their discussion on a copy of the inspection report (State Exhibit 71). Addendum #4 to Rhodes inspection report (State Exhibit 70) includes check marks for those items that Mark Graziano reported as corrected.

Ms. Rhodes notes from the meeting indicate, in part, that: the pharmacy technician's registration had been renewed, the unsecured outdated medications had been sent to a reverse distributor, someone was coming to destroy unsecured records stored in the basement, the pharmacist was wearing a name badge, the

controlled substances invoices had been signed and dated, there was a technician training policy and documentation of training, Schedule II invoices had been separated from Schedule III-V invoices, verification of control substance refills had been documented, and the pharmacy had started a signature log for dispensing medications in non-child proof containers. (Rhodes testimony; State Exhibits 70-71)

Only a few of the deficiencies in the sterile compounding area were reported as corrected. Media fill testing, microbial sampling, and pressure differential monitors were expected to be addressed in May. There were still no policies and procedures for sterile compounding. (Rhodes testimony; State Exhibits 70-71)

At hearing, Jean Rhodes explained the critical importance of the sterile compounding regulations to public health and safety. A company in Massachusetts had recently been cited for significant violations of sterile compounding regulations that resulted in patient illnesses and deaths. The Board's sterile compounding regulations provide a means to verify that pharmacies have a safe sterile compounding environment and to ensure that there are no microbes in the air that could contaminate the compounded product and potentially cause patient infection or death. In addition, pharmacies must also document that they have established proper policies, procedures, and training specific to sterile compounding. (Rhodes testimony)

Audit of ARCOS and PMP Records from 1/1/08-3/21/12 [First Audit]

7. Following the March 16th inspection, Compliance Officers Jean Rhodes and Sue Mears decided to audit the hydrocodone and oxycodone³ medications purchased and dispensed by Bauder Pharmacy from January 1, 2008 through March 21, 2012. For this audit, Rhodes and Mears reviewed records of drug orders maintained on the federal Automation of Reports and Consolidated Order System (ARCOS) and dispensing records maintained on the state Prescription Monitoring Program (PMP). (Rhodes testimony; State Exhibit 7, pp. 46, 49-50; State Exhibits 12-27)

- ARCOS is a database collected by the U.S. Department of Justice Drug Enforcement Administration (DEA), Office of Diversion Control. Drug manufacturers and wholesalers are required to report all orders of

³ Hydrocodone is a narcotic that is a Schedule III controlled substance. Oxycodone is a Schedule II controlled substance. (Rhodes testimony; See Iowa Code sections 124.206, 124.208)

Schedule I and Schedule II controlled substances and all narcotic controlled substances in Schedule III to ARCOS. Manufacturers and wholesalers report the ordering pharmacy's DEA number, a transaction date, and the trade name, drug code, quantity, dosage unit, dosage form, and national drug code for each drug that is ordered. (Rhodes, Jessen testimony; State Exhibits 18, 19)

- The Prescription Monitoring Program (PMP) was created by the Iowa legislature in 2009 to establish a central database of controlled substance prescriptions dispensed to patients in Iowa. At least twice a month, pharmacies must report all dispensing of Schedule II, III, and IV controlled substances to the PMP. The information reported must include the pharmacy's DEA number, the date that the prescription was filled, the prescription number, if the prescription is new or a refill, the NDC number for the drug, the quantity of the drug, the number of days of drug therapy provided by the drug as dispensed, patient information, the prescriber DEA number, the date the prescription was issued by the prescriber, and method of payment. (Rhodes testimony; See Iowa Code chapter 124.551-124.558; 657 IAC Chapter 37)

8. The results of the first audit are summarized in State's Exhibits 7 and 12. This audit revealed that for the period from January 1, 2008 to March 12, 2012:

- ARCOS records indicate that Bauder Pharmacy ordered and received a total of 1,098,900 hydrocodone APAP tablets (all brands, all strengths). The majority of the hydrocodone products were one strength, hydrocodone APAP 7.5/500 (593,700 tablets);
- PMP records indicate that Bauder Pharmacy dispensed 358,012 hydrocodone APAP tablets (all brands, all strengths) to customers;
- A total of 740,888 hydrocodone APAP tablets that were ordered from wholesalers could not be accounted for through Bauder Pharmacy's PMP dispensing reports. The vast majority of the unaccounted for hydrocodone products (530,336) were hydrocodone APAP 7.5mg/500mg.

The audit also broke down the number of unaccounted for hydrocodone APAP tablets by calendar year, as follows:

- Calendar Year 2008: 229,846 tablets;
- Calendar Year 2009: 163,185 tablets;

- Calendar Year 2010: 155,436 tablets;
- Calendar Year 2011: 182,732 tablets;
- January-March 2012: 9,689 tablets

The compliance officers also created spreadsheets and graphs showing monthly totals for all hydrocodone and all oxycodone products, as well as breakdown totals for each type of product. Jean Rhodes spoke to DEA agent William Siegert who estimated that the higher strength tablets of hydrocodone (7.5mg and 10mg) had a street value ranging from \$10-\$20 a pill. (Rhodes testimony; State Exhibits 7, 12-27)

9. During the March 16, 2012 inspection of Bauder Pharmacy, pharmacist in charge Mark Graziano told Jean Rhodes that Bauder Pharmacy used the following 4 wholesalers: Anda, McKesson, H.D.Smith, and Dakota Drug. Mr. Graziano told Rhodes that he used four suppliers because of drug shortages. (Rhodes testimony; State Exhibit 7, p. 49)

When reviewing the ARCOS records for Bauder Pharmacy, however, the compliance officers observed that Bauder Pharmacy had used 14 different wholesalers to purchase hydrocodone products during the audit period. The compliance officers also observed that Bauder Pharmacy had ordered Hydrocodone APAP 7.5/500mg from 5 different suppliers in 1 day on 1 occasion; from 4 different suppliers in 1 day on 3 occasions; from 3 suppliers in 1 day on 18 occasions; and from 2 different suppliers in 1 day on 75 occasions. (Rhodes testimony; State Exhibit 7, pp. 49-50; Exhibit 16)

Compliance Officer Sue Mears contacted two of Bauder Pharmacy's wholesalers to determine if they had experienced shortages of hydrocodone products. Anda reported some shortages of 5/325 and 5/500 strengths of hydrocodone that past fall. A representative of Top RX did not report any shortages but told Mears that some manufacturers may be reducing production levels of products with 500mg of APAP because by 2014 the FDA will no longer allow these products on the market. The Top RX representative also told Mears that his company requires a pharmacy to submit a usage report for the prior 3 months when filling out an initial application. If the controlled substance dispensing exceeds 30% of prescription volume, Top RX will not sell any controlled drugs to the pharmacy. (State Exhibit 7, p. 50)

10. Pharmacies are required to maintain complete and accurate records of all purchases and all dispensing or disposal of controlled substances. The purchase records must show the date of receipt, the name and address of the person from whom received, and the kind and quantity of drugs received. The records of all controlled substances dispensed or otherwise disposed of must show the date of dispensing, the name and address of the person to whom or for whose use, and the kind and quantity of drugs dispensed.

Pharmacies are required to maintain all records of controlled substances for at least two years from the date of the transaction. Prescriptions for controlled substances are valid for six months following the date of issue. A prescription for a Schedule III, IV, or V controlled substance may include authorization to refill the prescription no more than five times within the six months following issue. Controlled substance prescriptions must be maintained for two years from the last date of refill.

Inventories and other records of Schedule III, IV, and V records shall be maintained either separately from all other records or in a form so that the required information is readily retrievable from the pharmacy's ordinary business records. (Rhodes testimony; See also Iowa Code sections 124.306, 155A.12(4); 657 IAC 10. 21, 10.34, 8.9)

Pharmacists Kim Robertson and Jay Wangerin and pharmacy technician Jennifer Higgins all confirmed that Bauder Pharmacy received invoices from wholesalers with the delivery of their prescription drug orders. Following delivery, the pharmacist is responsible for checking in the controlled substance order and for signing and dating the invoice to document the shipment that was received. Invoices must be maintained in the pharmacy's records for a minimum period of two years. Pharmacist Kim Robertson was responsible for checking in all Schedule II controlled substances at Bauder Pharmacy. Either Ms. Robertson or another pharmacist checked in all other controlled substances. Mr. Wangerin told Board investigators that if he checked in controlled substances he always initialed and dated the invoice. (Rhodes, Jessen, Higgins testimony; State Exhibits 29-32; 657 IAC 8.9(1))

At the time of the March 16, 2012 pharmacy inspection, Bauder Pharmacy had approximately twenty years of controlled substance records stored in boxes in an unsecured area of the basement. Jean Rhodes informed Mark Graziano that the Board required controlled substance records to be kept for two years although

insurance companies may require records for a longer period of time. Mr. Graziano asked Rhodes if he could shred records that were more than two years old if he was only keeping them for the Board, and she told him that he could. The March 22, 2012 Inspection Report authored by Jean Rhodes states, in part: *"The basement is also an area of storage for pharmacy records. Recommended to destroy some of the very old records as the Board of pharmacy typically needs records for two years and insurance companies possibly for 10 years. Some records may be close to twenty years old that are stored in the basement."* (Rhodes, Mears testimony; State Exhibit 11, p. 58)

At hearing, Mark Graziano testified that the West Des Moines Lions Club shredded some of his old records on April 27, 2012. Mr. Graziano provided a receipt from the Lions Club showing that he paid \$200 for the "shred-it" on April 27, 2012. Mr. Graziano also testified that Jean Rhodes and/or the Board shredded his documents. This was not true. (Graziano, Rhodes testimony; Respondent Exhibit H)

Service of the Board's Statements of Charges, Orders, and Administrative Search Warrant

11. On May 3, 2012, the Board signed and issued an Order of Immediate Suspension and Order to Show Cause that immediately suspended Bauder Pharmacy Inc.'s controlled substance registration (number 1100280). The Board also found probable cause to file a Statement of Charges against Bauder Pharmacy, Inc., which alleged nineteen violations of state statutes and the Board's rules. (State Exhibits 4, 6) Also on May 3, 2012, the Board issued an Emergency Order that immediately suspended the pharmacist license (number 16752) issued to Mark Graziano. The Board also issued a Statement of Charges against Mark Graziano, which alleged 20 violations of state statutes and the Board's rules. (State Exhibits 1, 2)

On May 10, 2012, Jean Rhodes personally served the immediate suspension orders and the statements of charges on Bauder Pharmacy, Inc. and Mark Graziano. An administrative search warrant was served at the same time. The Board's Executive Director, several of the Board's compliance officers, and Matthew Sauer of the Iowa Division of Criminal Investigation (DCI) Cyber Crime Unit accompanied Rhodes to Bauder Pharmacy on May 10, 2012. (Rhodes, Jessen testimony; State Exhibit 28)

Mr. Sauer made a forensic image of the pharmacy's computer. Board staff seized all of the pharmacy's controlled substance records from January 1, 2008 through May 10, 2012 and all controlled substance medications. Pharmacist Kim Robertson and pharmacy technician Jennifer Higgins assisted the Board's compliance officers in attempting to locate the controlled substance records and medications, which were located throughout the pharmacy and in the basement of the building. Jean Rhodes told the pharmacy's employees to contact the Board if they located any additional controlled substance records for the relevant time period. The seized records and medications have been stored by the Board in locked, secure storage since May 10, 2012. (Rhodes, Jessen testimony; State Exhibit 28, pp. 492-493)

On May 10, 2012, the Board's compliance officers interviewed all Bauder Pharmacy employees, except Mark Graziano. The employees provided signed and witnessed voluntary statements and their interviews were also video recorded. The only employees who reportedly handled controlled substances as part of their duties were full-time pharmacists Mark Graziano and Kim Robertson, part-time pharmacist Jay Wangerin, and pharmacy technician Jennifer Higgins.

The employees reported that either Mark Graziano or Kim Robertson ordered controlled substances from the wholesalers. Kim Robertson checked in all Schedule II controlled substances. When asked how many wholesalers were used by the pharmacy to order controlled drugs, pharmacist Jay Wangerin identified 4 wholesalers and pharmacist Kim Robertson identified 3 wholesalers. (Rhodes testimony; State Exhibits 28, pp. 492-493; Exhibits 29-34)

Kirby Small Interviews and Testimony at Hearing

12. On May 11, 2012, Kirby Small called the Board office and identified himself as the person who had previously made the anonymous telephone complaint against Bauder Pharmacy. Jean Rhodes and Sue Mears interviewed Kirby Small that day, and he told them that he would be willing to testify. Ms. Rhodes took notes during this first interview. (State Exhibit 35) On May 15, 2012, Rhodes and Mears conducted a second interview of Kirby Small, which was video recorded. (State Exhibit 36)

During his two interviews, Kirby Small told the compliance officers that he was present many times when Mark Graziano would pass a box containing bottles of

hydrocodone APAP 7.5/500mg out the pharmacy's back door to a person that Small initially identified only as the "General." [Later in his interview, Kirby Small confirmed the identity of the General as well as two other persons he claimed were involved in the distribution of the hydrocodone] Mr. Small told Rhodes and Mears that he believed Mark Graziano had been illegally distributing hydrocodone since at least since 2005. Small believed that Mark Graziano used the money to cover his gambling losses and to pay for expensive cars. (Rhodes, Small testimony; State Exhibits 35, 36)

Kirby Small told Rhodes and Mears that he had been using 15-20 hydrocodone tablets a day for years and would receive 100 hydrocodone tablets from the General every week. Small told them that prior to making his anonymous report, the General and Mark Graziano refused to give him any more hydrocodone because he was unable to pay them. Mr. Small reports that after the General cut him off, he confronted Mark Graziano in the Bauder Pharmacy parking lot and told Graziano that he "knew everything." When Mark Graziano responded by telling Small that he did not know what he was talking about, Small admits he "went crazy" and told Graziano that he would not be able to "keep doing this."

According to Mr. Small, Pharmacist Kim Robertson came out to the parking lot and told Mark he had a telephone call. After Mark went back inside the pharmacy, Small told Kim that Mark was selling hydrocodone out the back door of the pharmacy and would "ruin you." Kim reportedly told Small "you need help." According to Mr. Small, Mark Graziano later called and threatened him with sending some "guys" over to his house. Mr. Small did not believe this threat, and no one ever came to his house. (Rhodes, Small testimony; State Exhibits 35, 36)

Kirby Small reported that he was forced to go "cold turkey" and stop taking hydrocodone after the General and Mark Graziano cut off his supply. He reports that he spent three days on the couch, "jonesing" and was unable to eat. After he was finally free of the drugs and felt better, Mr. Small realized how much the hydrocodone had damaged his life and how much it was hurting others. This motivated him to come forward and testify. (State Exhibits 35, 36; Small testimony)

During his interview, Kirby Small admitted that he was on criminal probation for a "Department of Human Services thing" at the time he confronted Mark

Graziano. On cross-examination at hearing, Kirby Small admitted that he had been convicted of elderly abuse for misusing his father's money. Mr. Small believes that Mark Graziano or the General called his probation officer to report that he had been smoking marijuana. Mr. Small was arrested for a probation violation and sent to jail for 15 days. If his probation had been revoked, Mr. Small would have been required to serve a five year prison sentence. Mr. Small admits this is what prompted him to make the initial anonymous telephone call to the Board in late September, 2011. Kirby Small later identified himself as the anonymous complainant after seeing the news report on the Board's visit to the pharmacy and filing of charges. (Small testimony; State Exhibit 28, p. 494; Exhibits 35, 36)

At hearing, Kirby Small described what happened the times that he went with "the General" to Bauder Pharmacy to pick up the hydrocodone. Mr. Small testified that he and the General would be out for coffee on a Saturday morning, and the General would call Mark Graziano to arrange the pick-up. Mr. Small testified that the hydrocodone pick-up usually occurred after 9:00 a.m. because the UPS truck delivered the hydrocodone to the pharmacy at around 9:00 a.m. (Small testimony; State Exhibits 35, 36)

Kirby Small testified that on some occasions he drove around to the back of the pharmacy and waited outside while the General went in the back door of the pharmacy to get the hydrocodone. Other times, he would drop the General off at the front of the pharmacy and then drive around to the back of the pharmacy to wait for him. The General would come out the pharmacy's back door with a box containing 2-3 white stock bottles of 7.5mg hydrocodone. The "General" removed the labels from the bottles and got rid of them. Small testified that after the pick-up, he sometimes helped the General count the pills. After one of the pill counting sessions, Mr. Small kept one of the pharmacy stock bottles as a "souvenir." He brought the stock bottle, which did not have any label on it, to his interview at the Board office and to the hearing.⁴ (Small testimony; State Exhibit 79)

⁴ In his statements and in testimony at hearing, Mr. Small sometimes described the 7.5mg hydrocodone stock bottles as containing 5000 tablets and sometimes described them as containing 500 tablets. The hearing record does not contain any documentation that Bauder Pharmacy ever received stock bottles containing 5000 tablets, but there are many records for stock bottles containing 500 tablets. The stock bottle provided by Mr. Small (State Exhibit 79) appeared consistent in size with a 500 tablet stock bottle.

Kirby Small was unclear on how many times he went with the General to Bauder Pharmacy for the hydrocodone pick up. Initially, he testified that he went with the General probably no more than 10 times but later clarified that he meant “at least” 10 times. Mr. Small testified that the General also picked up hydrocodone from Bauder Pharmacy on many other occasions without him. (Small testimony)

At hearing, Mark Graziano denied ever having anything to do with Kirby Small other than filling his prescriptions and allowing Small to do some painting at his home when Small was unable to pay his bill at the pharmacy. Mr. Graziano admitted that he and Kirby Small know some people in common, but denied illegally distributing hydrocodone and denied that he ever threatened Kirby Small. (Small, Graziano testimony)

***Bauder Pharmacy Audit Using Wholesaler Records and Computer Records
from 1/1/08-3/21/12 [Second Audit]***

13. After the administrative search warrant was executed, Jean Rhodes and Sue Mears conducted a second audit using the invoices subpoenaed from Bauder Pharmacy's wholesalers, the invoices seized from Bauder Pharmacy, and the actual controlled substance dispensing records from the pharmacy's computer. The results of the second audit are summarized in State Exhibit 28. The second audit revealed that for the period from January 1, 2008 to March 12, 2012:

- The wholesaler verified invoices show that Bauder Pharmacy ordered and received a total of 1,049,300 hydrocodone APAP tablets (all brands, all strengths). Of these, 495,311 tablets were hydrocodone APAP 7.5/500;
- PMP records indicate that Bauder Pharmacy dispensed 359,313 hydrocodone APAP tablets (all brands, all strengths) to customers;
- There were 689,987 hydrocodone APAP tablets that were ordered and shipped to Bauder Pharmacy by wholesalers that could not be accounted for through the pharmacy's computerized dispensing records.

(Rhodes testimony; State Exhibit 28, pp. 495-496)

14. Rhodes and Mears created detailed spreadsheets comparing and analyzing the information obtained in the two audits. State Exhibits 37-44 are spreadsheets that list every wholesaler invoice and indicate whether the invoice was reported to ARCOS, whether it was provided by the wholesaler in response

to the Board subpoena, and whether the same invoice was found in the records maintained by Bauder Pharmacy. (Rhodes testimony; State Exhibits 37-55)

a) Auburn was the only wholesaler that was unable to provide invoices for the entire audit period because it only had invoices going back as far as November 4, 2009. Because of this, the second audit was unable to verify 33,500 hydrocodone tablets that Auburn reported to ARCOS as having been ordered by Bauder Pharmacy in 2008 and was unable to verify 33,000 hydrocodone tablets from 2009. These unverified tablets were not included in the second audit and resulted in a lower number of purchases than those that had been reported in ARCOS. (State Exhibit 28, p. 495; Rhodes testimony)

b) For calendar year 2008, wholesaler Masters Pharmaceutical provided five invoices in response to the Board's subpoena that it had not been previously reported to ARCOS. These invoices were for an additional 2000 tablets of hydrocodone APAP 5/500mg and 2000 tablets of 7.5/500mg. (State Exhibit 28, p. 495; State Exhibit 37, p. 519-520, 527-528).

c) For calendar year 2009, all of the wholesaler's invoices matched the orders reported to ARCOS with the exception of the invoices that Auburn had not retained. (State Exhibit 28, p. 495; Exhibit 38)

d) For calendar year 2010, wholesaler Dakota Drug provided an invoice for 1000 tablets of hydrocodone APAP 7.5/500mg that had not been reported to ARCOS. (State Exhibit 28, p. 495; Exhibit 39, pp. 585-586).

e) For calendar year 2011, the following drugs were reported to ARCOS but were later returned to the wholesalers by Bauder Pharmacy: 100 tablets hydrocodone APAP 10/325mg returned to Cardinal; 1000 tablets hydrocodone APAP 10/325mg returned to Top RX; and 1000 tablets hydrocodone APAP 7.5/500mg returned to Top RX. (State Exhibit 28, p. 495, Exhibit 40, pp. 597-598, 602).

f) For calendar year 2012, wholesaler Auburn provided two invoices in response to the Board's subpoena that had not been reported to ARCOS. These included an invoice for 2000 tablets of hydrocodone APAP 7.5/500mg and an invoice for 1000 tablets hydrocodone APAP 10/325mg. (State Exhibit 28, p. 496; Exhibit 41).

g) Bauder Pharmacy was missing 137 invoices for its purchases of 144,000 tablets of hydrocodone APAP 7.5/500mg product during calendar years 2010, 2011, and 2012. Bauder Pharmacy should have been able to provide these invoices because they fell within the two year period for retention of controlled substances records. (State Exhibit 28, p. 497).

h) Bauder Pharmacy was also missing its annual inventories of hydrocodone products. (State Exhibit 28, p. 496).

i) A total of 907 hydrocodone tablets that were documented as having been dispensed per Bauder Pharmacy's computer dispensing records had not been reported by Bauder Pharmacy to the PMP. (State Exhibit 28, p. 496)

(Rhodes testimony)

15. On June 20, 2012, Jean Rhodes and Sue Mears met with pharmacist Kim Robertson at Bauder Pharmacy. At this visit, Jean Rhodes reminded Ms. Robertson that the pharmacy still needed to identify a new pharmacist in charge. Rhodes and Mears showed Ms. Robertson the 2010 and 2011 invoices that she had signed and asked her if she could explain the large discrepancy between the amount of hydrocodone APAP 7.5/500mg that she was signing for each month and the small amount that the pharmacy was dispensing.

- In 2010, Kim Robertson signed invoices for receipt of a total of 62,500 tablets of hydrocodone APAP 7.5/500mg, but the pharmacy's records showed that only 14,949 tablets had been dispensed. This meant that 47,551 tablets were not accounted for;
- From January to September of 2011, Kim Robertson signed invoices for a total of 58,500 tablets of hydrocodone APAP 7.5/500mg, but the pharmacy's records showed that 7,532 tablets were dispensed. This meant that 50,968 tablets were not accounted for.

Kim Robertson denied that any drug diversion was going on at the pharmacy and told Rhodes that she would only order the hydrocodone if there were prescriptions for it. Ms. Robertson also questioned whether the computer records could be wrong and asked to see the invoices. (Rhodes testimony; Exhibit 28, p. 496-497; Exhibits 43-44)

Jean Rhodes also informed Kim Robertson that the pharmacy had a large number of missing invoices and that the annual inventories of hydrocodone products were also missing. Ms. Robertson replied that she was sure the inventories were in the yellow notebook or in the front of the perpetual CII log. Rhodes and Mears returned to the secure storage area where the Bauder Pharmacy records were being kept and reviewed the CII perpetual log and the yellow notebook. The hydrocodone inventories were not there. (Rhodes testimony; Exhibit 28, p. 496)

16. On July 23, 2012, Bauder Pharmacy submitted a pharmacist in charge (PIC) change naming Kim Robertson as the new PIC. (Rhodes testimony; State Exhibit 56, p. 753-754)

Review of Randomly Selected Prescriptions Filled by Bauder Pharmacy 2008-2012

17. Jean Rhodes and Sue Mears reviewed 614 randomly selected prescriptions that had been filled by Bauder Pharmacy between 2008 and 2012. Only 166 of the 614 prescriptions met all of the legal requirements for prescriptions. The various deficiencies on these prescriptions included:

- Sender's information cut off from fax;
- Wrong patient;
- Wrong prescriber;
- Wrong medication;
- No prescriber signature or verification;
- Wrong number of refills;
- Wrong directions;
- No prescriber DEA number for controlled substances;
- Faxed prescription not signed by prescriber;
- Wrong dispensed quantity;
- Filled beyond authorized time period;
- Filled prior to authorization;
- RX denied by prescriber but filled by pharmacy;
- No prescribed quantity;
- RX number not recorded on prescription;
- Dispensed generic when prescription indicated "Do not substitute."

(Rhodes testimony; State Exhibit 56, pp. 753-755; Exhibits 57-61)

18. Jean Rhodes and Sue Mears conducted a separate review of the Androgel prescriptions filled by Bauder Pharmacy after their invoice review revealed frequent purchases of Androgel by the pharmacy. Androgel (testosterone) is a Schedule III controlled substance. Rhodes and Mears reviewed a total of 95 Androgel prescriptions filled by Bauder Pharmacy between 2010 and 2012. Only 3 of the 95 prescriptions were found to be legally correct. The deficiencies on the Androgel prescriptions included:

- No Dr. DEA number;
- No hardcopy in file;
- No prescriber signature;
- Stamped prescriber signature;
- Unauthorized refills dispensed;
- Refilled beyond 6 months;
- Initial fill after the prescription had expired (6 months);
- No patient name on hard copy prescription;
- No notation of verbal authorization;
- No RX number on prescription;
- Sender information cut off from fax;
- Wrong dosage form of medication;
- Filled prior to receipt of fax authorization.

(Rhodes testimony; State Exhibit 56, pp. 755-756; State Exhibits 62-64)

19. Jean Rhodes and Sue Mears visited the physician offices for three patients who had Androgel prescriptions filled by Bauder Pharmacy between August 2009 and April 2012. The purpose of these visits was to verify the validity of the prescriptions.

a) Bauder Pharmacy filled 9 prescriptions for Androgel in the name of Patient #1 between January 25, 2010 and April 21, 2012. Patient #1's physician's office could only verify 4 of the prescriptions. Bauder Pharmacy had dispensed a total of 420 unauthorized 1% 5gm gel packets in the name of this patient.

b) Bauder Pharmacy filled 6 prescriptions for Androgel in the name of Patient #2 between January 20, 2010 and April 30, 2012. Patient #2's physician's office could only verify 3 of the prescriptions. Bauder Pharmacy had dispensed a total of 600 unauthorized 1% 5gm gel packets in the name of this patient.

c) Bauder Pharmacy filled 8 prescriptions for Androgel in the name of Patient #3 between August 15, 2009 and April 30, 2012. Patient #3's physician's office could only verify 5 of the prescriptions. Bauder Pharmacy had dispensed a total of 450 unauthorized 1% 5gm gel packets in the name of this patient.

(Rhodes testimony; State Exhibit 56, p. 756; State Exhibit 65)

Review of Prescriptions for CG

20. During the initial audit, Jean Rhodes noted that CG was the only patient receiving brand name Lortab (Hydrocodone and Acetaminophen 7.5/500mg) from Bauder Pharmacy, and there were several early refills. CG is a family member of Mark Graziano. Jean Rhodes contacted CG's physician's office in an attempt to verify if he had authorized the patient's Lortab prescriptions. She obtained statements from the physician's staff members but it is unclear if she ever spoke to CG's physician. Ms. Rhodes determined that since July 18, 2011, Bauder Pharmacy had filled 5 unauthorized prescriptions for CG and had provided an additional 8 unauthorized refills. (Rhodes testimony; State Exhibit 56, pp. 756-757; Exhibit 66-69)

At hearing, Respondents submitted a February 25, 2013 letter from CG's physician, in which he states that he first met CG in January 2009. According to the letter, CG was on Alprazolam and hydrocodone when the physician first met her, still is, and has been as long as he has known her. (Respondent Exhibit L) Respondents also submitted a March 6, 2012 prescription written by the physician for CG for hydrocodone/acetaminophen 7.5/500. (Respondent Exhibit M)

At hearing, Mark Graziano testified that CG is usually accompanied to her doctor appointments by one of her four family members who are licensed pharmacists. Mr. Graziano further testified that it is not unusual for the physician to give direct verbal authorization for CG's prescriptions to one of the pharmacists in CG's family. (Graziano testimony)

Rhodes' Return to Bauder Pharmacy on October 11, 2012

21. On October 11, 2012, Jean Rhodes revisited Bauder Pharmacy and met with pharmacist in charge Kim Robertson to review the deficiency corrections

from the March 22, 2012 Inspection Report. Mark Graziano was behind the pharmacy counter when Ms. Rhodes entered the store. Ms. Robertson denied that Mr. Graziano was performing any pharmacist duties and told Rhodes that he was helping with the billing.

Ms. Rhodes asked to see the pharmacy's policies and procedures manual. Ms. Robertson checked with Mr. Graziano and they both claimed that the Board had taken the policies and procedures with all of the other records. Mr. Graziano stated that the policies and procedures were in the back of a black book. Following the visit, Ms. Rhodes reviewed the records in the Board's possession. The only black book was the daily controlled substance refill log. She then notified Ms. Robertson that the Board does not have possession of the pharmacy's policies and procedure manual. (Rhodes testimony; State Exhibit 70, pp. 815-816)

The pharmacy still did not have a Continuous Quality Improvement (CQI) program at the time of Rhodes' revisit, nor did it have a documented technician training policy. Ms. Rhodes also needed to verify that no legend medications or pharmacy records were being stored in the unsecured basement. Mr. Graziano had previously reported that medications had been sent to a reverse distributor and that someone was coming to destroy records. Upon checking the basement, Ms. Rhodes found hardcopy prescriptions from 2007 and also found shelves of older medications. (Rhodes testimony; State Exhibit 70, pp. 815-816; Exhibits 71A, 72, 73)

Respondents' Evidence at Hearing

22. Pharmacy technician Jennifer Higgins has been employed by Bauder Pharmacy for eight years. Ms. Higgins testified that Kim Robertson was primarily responsible for checking in the shipments of controlled substances to the pharmacy. If Ms. Higgins opened a tote from a wholesaler and saw controlled substances in it, she would give the shipment to Ms. Robertson. Ms. Higgins was working at Bauder Pharmacy when Jean Rhodes conducted the March 16, 2012 inspection. Ms. Higgins testified that she was present when Ms. Rhodes presented Kim Robertson with a "stack" of unsigned invoices that had been collected and told her to sign them. Ms. Higgins did not actually observe Ms. Robertson sign these invoices. (Higgins testimony)

Only a pharmacist could place an order for a controlled drug at Bauder Pharmacy. After the controlled substances were checked in, Ms. Higgins might help put Schedule III-V controlled substances on the shelf. She estimated that they usually had about 2-3 bottles of 7.5/500 mg hydrocodone on the shelf at one time. Ms. Higgins never observed anyone take a stock bottle of hydrocodone out the back door of the pharmacy. (Higgins testimony)

23. In his testimony at hearing, Mark Graziano admitted that at the time of the March 16, 2012 pharmacy inspection:

- Jennifer Higgins' pharmacy technician registration had been expired since September 30, 2010. Mr. Graziano testified that he did not realize it had expired but admitted that as the PIC he was responsible for Ms. Higgins;
- Bauder Pharmacy did not have written policies and procedures, which are the responsibility of the PIC;
- There were outdated medications that were in an unsecured location in the basement;
- He was not wearing his identification badge. Mr. Graziano testified that he did not think the ID badge was necessary because all of his customers know him;
- All of the pharmacy's invoices were not signed;
- The only documentation of pharmacy technician training was on a notecard;
- The pharmacy did not have a written Continuous Quality Improvement (CQI) program. Mr. Graziano further admitted that he did not even know that a CQI program was required;
- There were a number of deficiencies involving the pharmacy's sterile compounding, including violations of the rules requiring: policies and procedures, a quality assurance program, documentation of training, and environmental testing. Mr. Graziano testified that he had been doing sterile compounding for four years but was not familiar with the federal rules for sterile compounding (USP 797) and had little knowledge of the Board's rules on sterile compounding.

(Graziano testimony)

24. Mark Graziano admits that as PIC, he was responsible for the security of the pharmacy and for establishing policies and taking steps to prevent illegal

diversion of drugs. Mr. Graziano provided the following testimony concerning the pharmacy's process for ordering and receiving controlled drugs:

- Mr. Graziano ordered controlled substances for the pharmacy, although the other two pharmacists could also place orders. He placed orders in one of three ways: in response to a telephone solicitation by a wholesaler's sales representative, on-line through the wholesaler's website, and by telephone. The majority of orders were placed by phone;
- When orders were placed on-line through a website, the person placing the order had to enter a User ID and a password. Mr. Graziano had trouble remembering his User ID and passwords and kept them on a "cheat" sheet underneath his computer;
- The majority of the pharmacy's controlled substance purchases were linked to the VISA credit card issued in the name of Mark Graziano/Bauder Pharmacy. The credit card had a \$50,000 limit, but the monthly charges on it were sometimes as high as \$75,000; and
- The controlled substance orders were delivered by various carriers and would arrive in either a tote or a box with the invoice. Kim Robertson was primarily responsible for checking in the controlled substance orders and signing off on the invoice, although any pharmacist could check them in. The invoices were filed in the basement.

Mark Graziano denies ever illegally dispensing hydrocodone from Bauder Pharmacy without a prescription and denies all of the claims of illegal distribution of hydrocodone made by Kirby Small. Mr. Graziano testified that he did not know that any drugs were missing from the pharmacy prior to May 2012 and if he had known, he would have notified the Board and the DEA. (Graziano testimony)

When asked how he explained the hydrocodone that could not be accounted for through the pharmacy's records, Mr. Graziano testified that the Board "made him" shred his older records. Mr. Graziano testified that the missing invoices were probably in the wrong box and likely were shredded in late April 2012. He suggests that the missing invoices would help exonerate him of the charges of illegally dispensing hydrocodone. (Graziano testimony)

Mark Graziano testified that there were occasions when it appeared to him that someone had tampered with the security tape on boxes delivered to the pharmacy. Mr. Graziano estimated that Bauder Pharmacy received boxes from

wholesalers that appeared to have been tampered with on 10-20 occasions. Mr. Graziano further testified that when this happened he refused to accept the shipment and notified the manufacturer. Mr. Graziano never reported any tampering or missing drugs to the police or to the Board. (Graziano testimony)

Mark Graziano also testified that drug orders were sometimes shipped to Bauder Pharmacy in error. He submitted documentation of one incident that occurred in January 2013. Dakota Drug mistakenly sent a shipment of hydrocodone APAP TB 10/235 to Bauder Pharmacy, when the shipment was intended for a pharmacy in Mason City. Bauder Pharmacy immediately notified the Board and Dakota Drug of the error, and the shipment was returned. Mr. Graziano questioned how Dakota Drug would have reported the order to ARCOS if Bauder Pharmacy had not alerted the Board. (Respondent Exhibit F; Graziano testimony)

After this mistake was reported, Jean Rhodes contacted Dakota Drug to inquire if these types of errors were very common. The shipping supervisor advised Rhodes that packages must go through at least three people prior to shipment, but that there is always the possibility of human error. He was not aware of any statistics that the company kept on errors. (State Exhibit 75)

Mark Graziano further testified that someone has had unauthorized access to his VISA credit cards, and he believes that his credit cards may have been used by someone else to order hydrocodone from his wholesalers. Mr. Graziano provided three partial VISA credit card statements (May 2010, April 2011, and May 2012) issued in the name of Mark E. Graziano/Bauder Pharmacy. The three credit card statements all had different account numbers. Mr. Graziano testified that he had to open the new accounts because the old accounts had been "tampered with." (Graziano testimony)

Mark Graziano did not explain what caused him to believe that the credit card accounts had been tampered with, and he did not provide any other information concerning these accounts. Mr. Graziano admits that even after he believed that his credit card accounts had been compromised, he never compared his billing statements to his invoices to check for improper charges. He testified that he just assumed that any charges on his credit cards from his drug wholesalers were legitimate. Mr. Graziano testified that he did not connect the compromise of his credit cards to the hydrocodone shortages until just a few days prior to hearing. At hearing, Mr. Graziano suggested that someone who worked at the pharmacy

may have used his credit card to purchase controlled substances. (Graziano testimony)

CONCLUSIONS OF LAW

Board's Authority to Discipline Licensees and Registrants

The Board is authorized to discipline pharmacists and pharmacies for any violation of Iowa Code chapters 155A, 124 or any rule of the Board. Specifically, Iowa Code section 155A.15(2)(c) and (h) authorize the Board to impose discipline, including but not limited to revocation, if it finds that a *licensed pharmacy* has:

c. Violated any provision of this chapter or any rule adopted under this chapter or that any owner or employee of the pharmacy has violated any provision of this chapter or any rule adopted under this chapter.

...

h. Failed to keep and maintain records as required by this chapter, the controlled substances Act, or rules adopted under the controlled substances Act.

Iowa Code section 124.304(1)(d) also authorizes the Board to suspend, revoke, or restrict a controlled substances registration, issued under section 124.303 to manufacture, distribute, or dispense a controlled substance, upon a finding that the registrant committed such acts as would render the registrant's registration under section 124.303 inconsistent with the public interest, as determined under that section. The Board may suspend any registration simultaneously with the institution of disciplinary proceedings under section 124.304 if it finds that there is an imminent danger to the public health and safety which warrants this action.⁵

Iowa Code section 124.303(1) sets out the factors that the Board may consider in determining whether issuance of a controlled substance registration would be inconsistent with the public interest. The factors include, in relevant part: the registrant's maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels and the registrant's compliance with applicable state and local law.

⁵ Iowa Code section 123.305(2).

Iowa Code section 155A.12(1), (4), and (5) authorize the Board to impose discipline, including revocation, on any *licensed pharmacist* who:

1. Violated any provision of this chapter or any rules of the board adopted under this chapter.
- ...
4. Failed to keep and maintain complete and accurate records required by this chapter or failed to keep and maintain complete and accurate records of purchases and disposal of drugs listed in the controlled substances Act.
5. Violated any provision of the controlled substances Act or rules relating to that Act.

Iowa Code section 17A.18 and 657 IAC 35.30 authorize the Board to issue an Emergency Adjudicative Order taking immediate action to suspend a license or registration when necessary to prevent or avoid immediate danger to the public health, safety or welfare.

***Count I : Bauder Pharmacy and Mark Graziano
Failing To Maintain Effective Controls and Accountability Over Controlled
Substances***

Iowa Code section 124.402(1) (a) provides that it is unlawful for any person, subject to Division III (Regulation of the Manufacture, Distribution, and Dispensing of Controlled Substances), to distribute or dispense a controlled substance in violation of section 124.308. Iowa Code section 124.308(4) prohibits pharmacies from dispensing a controlled substance included in Schedule III or IV without a written or oral prescription of a practitioner or without an electronic or facsimile prescription in accordance with subsection 5. The prescription for a Schedule III Controlled Substance may not be filled or refilled more than six months after its issue date and may not be refilled more than five times, unless renewed by the practitioner.

A substance is placed in Schedule III if it has a potential for abuse that is less than that of substances in Schedules I and II, if the substance has a currently accepted medical use in treatment, and if abuse of the substance may lead to

moderate or low physical dependence or to high psychological dependence.⁶ Hydrocodone is a narcotic drug that has been placed in Schedule III.⁷

657 IAC 36.1(ac) authorizes the Board to discipline any licensee, registrant, or permittee who fails to create and maintain complete and accurate records as required by state or federal law, regulation or rule of the Board.

The preponderance of the evidence established that Respondent Bauder Pharmacy violated Iowa Code sections 155A.15(2)(c) and (h), 124.402(1), 124.308 and 657 IAC 36.1(4(ac) when it failed to maintain adequate control over and accountability for controlled substances by failing to keep and maintain all required records of controlled substances and by failing to prevent loss or diversion of controlled substances from the pharmacy.

The preponderance of the evidence established that Respondent Mark Graziano violated Iowa Code sections 155A.12(1),(4), and (5), 124.402(1), 124.308 and 657 IAC 36.1(4(ac) when he failed to maintain adequate control over and accountability for controlled substances by failing to keep and maintain all required records and by failing to prevent loss or diversion of controlled substances from the pharmacy. As the pharmacist in charge (PIC), Mark Graziano was responsible for maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs.⁸ He was also responsible for establishing and maintaining effective controls against the theft or diversion of prescription drugs and for maintaining records for such drugs.⁹

The preponderance of credible evidence in the record established that Bauder Pharmacy is unable to account for over 650,000 tablets of hydrocodone it received during the period of time covered by the Board's two audits. Board staff conducted painstaking and detailed audits to identify this large number of unaccounted for hydrocodone tablets. The two audits yielded very similar results when the missing invoices from wholesaler Auburn (those before November 4, 2009) are taken into account. The first audit indicated that Bauder Pharmacy could not account for 740,888 hydrocodone tablets, while the second audit indicated that Bauder Pharmacy could not account for 689,987

⁶ Iowa Code section 124.207.

⁷ Iowa Code section 124.208(5).

⁸ 657 IAC 6.2(12).

⁹ 657 IAC 6.2(13).

hydrocodone tablets. It is impossible to calculate a precise count of the missing hydrocodone, due in large part to Respondents' repeated failures to properly create and maintain accurate records for controlled substances. Nevertheless, overwhelming evidence established that a gross quantity of hydrocodone tablets have been illegally diverted from Bauder Pharmacy and/or were dispensed from the pharmacy in violation of Iowa Code chapters 124, 155A, and the Board's rules. The preponderance of the credible evidence in the record further established that pharmacist in charge Mark Graziano was involved in the illegal diversion of large quantities of hydrocodone from Bauder Pharmacy.

Mark Graziano testified that he "stands by" the accuracy of the controlled substance dispensing reports that he made to the PMP. In fact, the number of hydrocodone prescriptions recorded on Bauder Pharmacy's computer system for the period of the audit was quite close to the number of hydrocodone prescriptions reported by Bauder Pharmacy to the PMP. (358,012 v. 359,313 tablets dispensed).

The number of hydrocodone tablets that Bauder Pharmacy dispensed by prescription stands in stark contrast to the far larger numbers of hydrocodone that Bauder Pharmacy ordered from wholesalers over the same period (per ARCOS records-1,098,900 hydrocodone tablets; per wholesaler verified invoices-1,049,300 tablets). Mark Graziano does dispute the accuracy of the ARCOS records, however. Through the second audit examining the actual invoices, the Board's compliance officers did identify a few errors in the ARCOS reports (although the errors were reporting omissions.) Nevertheless, it is also clear that the number of reporting errors is likely very small in comparison to the number of transactions that wholesalers reported. Errors in the ARCOS reports cannot possibly account for the huge discrepancies between Bauder Pharmacy's hydrocodone orders and its dispensing records.

As the pharmacist in charge, Mark Graziano was responsible for ensuring that Bauder Pharmacy created and maintained all required controlled substance records. State statutes and Board rules require most of these records, including invoices, to be kept for a minimum period of two years. The records are required to be organized and readily retrievable by an agent of the Board.

Mark Graziano made repeated claims throughout his testimony suggesting that either Jean Rhodes or the Board shredded his records, thereby undermining his ability to defend himself against these charges. This is completely untrue and

unsupported by the record. When Jean Rhodes arrived at Bauder Pharmacy to conduct the inspection on March 16, 2012, the pharmacy's controlled substance records were neither organized nor readily retrievable. A large number of records, including confidential patient records and other records close to 20 years old, were improperly stored in an unsecured area of the pharmacy's basement. Ms. Rhodes reasonably advised Mr. Graziano that he should get rid of some of the older records, and her inspection report clearly states, in bold print, that insurance companies may require records for up to 10 years. There is no evidence that Ms. Rhodes or the Board destroyed any records or directed Mr. Graziano which records he should destroy. Mr. Graziano submitted his \$200 receipt from the West Des Moines Lion Clubs for shredding some of the records. Mr. Graziano is the person responsible if records were misfiled and destroyed because he failed to verify the contents of boxes that he gave to the shredder.

As the pharmacist in charge and the person primarily responsible for ordering the hydrocodone, Mark Graziano must have been known the enormous numbers of hydrocodone tablets that Bauder Pharmacy was ordering from wholesalers. Over the period of the audit, Mr. Graziano ordered hydrocodone from 14 different wholesalers and frequently ordered hydrocodone from multiple different wholesalers in a single day. It is obvious to the Board that this was a strategy employed by Mark Graziano to try to conceal the large numbers of hydrocodone that he was ordering. It is significant that when Jean Rhodes asked Mark Graziano how many wholesalers he used to order controlled substances, he reported using only 4 wholesalers. Bauder's two other pharmacists reported that the pharmacy used 3 or 4 wholesalers. The wholesaler records show, however, that Bauder Pharmacy had in fact ordered hydrocodone from 7 different wholesalers in the first three months of 2012. (State Exhibit 41) In 2011, Bauder Pharmacy ordered hydrocodone from 11 different wholesalers. (State Exhibit 40) In 2010, Bauder Pharmacy ordered hydrocodone from 8 different wholesalers. (State Exhibit 41)

Some hydrocodone shipments may have arrived at Bauder Pharmacy in boxes that were damaged or appeared to have been tampered with. Some controlled substances may have been shipped to Bauder Pharmacy in error. The Board is convinced, however, that this would have constituted a very small percentage of the overall number of hydrocodone shipments to Bauder Pharmacy. Moreover, Mark Graziano and Bauder Pharmacy were responsible for ensuring that all controlled substance shipments received at the pharmacy were checked against invoices for accuracy before the invoices were signed and dated. This is an

essential step in maintaining accurate records. Mark Graziano and Bauder Pharmacy were required to properly report and document any missing drugs or any return of drugs received in error.

In his testimony, Mark Graziano suggested that an unnamed employee could have had access to his user name and password and could have ordered hydrocodone from wholesalers using his credit card, which he reports was compromised three years in a row. This testimony was neither credible nor plausible. Mr. Graziano provided no evidence to show that his credit card had ever been used to make hydrocodone purchases that he did not authorize. If the Bauder Pharmacy credit card had been compromised as Mark Graziano claims, it is completely implausible that he, as a small business owner, would continue to pay credit card balances in the range of \$50,000 every month without ever checking his statements for errors or unauthorized charges. Finally, as the pharmacist in charge Mr. Graziano was responsible for ensuring that proper security controls were in place for the pharmacy. This includes taking reasonable steps to protect his user name, password, and the credit card he had authorized to be charged for hydrocodone purchases.

Although there were some inconsistencies in Kirby Small's statements and testimony, the Board ultimately determined that Mr. Small's statements and testimony about the illegal distribution of hydrocodone from Bauder Pharmacy were more reliable and more plausible than Mark Graziano's denials. Mr. Small initially reported Mark Graziano's illegal distribution of hydrocodone in an anonymous telephone call to the Board nearly six months before the Board's first audit that revealed the large numbers of missing hydrocodone tablets.

From his first contact with Board staff, Mr. Small readily admitted that he was a drug user who was addicted to hydrocodone. After the Board's charges were made public, Mr. Small came forward to the Board and identified himself and also named others allegedly involved in the illegal distribution. He admitted that he had a criminal record. Mr. Small had nothing to gain from going public with his report, and he risked possible retribution and prosecution. Mr. Small has provided the only plausible explanation for what happened to the hundreds of thousands of hydrocodone tablets that Mark Graziano and Bauder Pharmacy cannot account for.

***Count II: Bauder Pharmacy and Mark Graziano
Inadequate Security and Failure to Establish Effective Controls Against
Diversion***

657 IAC 10.15 requires all registrants to provide effective controls and procedures to guard against theft and diversion of controlled substances. The rule sets forth a number of factors for the Board to consider when evaluating a registrant's security system. The factors with particular relevance to this case include: the adequacy of supervision over employees having access to controlled substances and storage areas, the extent of unsupervised public access to the facility, and the adequacy of the registrant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances. 657 IAC 10.15(2)"i,""j," and "m."

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 10.15 by failing to provide effective controls and procedures to guard against the theft and diversion of controlled substances. All of the reasons cited in connection with Count I also support a finding of violation under this count. Bauder Pharmacy's system for monitoring the receipt, distribution, and disposition of controlled substances was wholly inadequate. In addition, Respondents stored expired controlled drugs in an unlocked and unsecured area of the basement, which could potentially be accessed by unlicensed employees and the public.

***Count III: Bauder Pharmacy and Mark Graziano
Failure to Keep and Maintain Records Required by the Controlled Substances
Act***

Iowa Code section 124.306 provides that persons registered to manufacture, distribute, dispense or administer controlled substances under Iowa Code chapter 124 shall keep records and maintain inventories in conformance with the recordkeeping and inventory requirements of federal law and such additional rules as may be issued by the Board. A practitioner who engages in dispensing any controlled substances to the practitioner's patients shall keep records of receipt and disbursements of such drugs, including dispensing or other disposition, and information as to controlled substances stolen, lost, and destroyed. In every such case the records of controlled substance received shall show the date of receipt, the name and address of the person from whom received, and the kind and quantity of drugs received. The record of all

controlled substances dispensed or otherwise disposed of, shall show the date of dispensing, the name and address of the person to whom or for whose use, or the owner and species of animal for which the drugs were dispensed and the kind and quantity of drugs dispensed.

“Practitioner” is statutorily defined to include a pharmacy. Iowa Code section 124.101(26)(b).

Iowa Code section 124.306 further provides that every such record shall be kept for a period of two years from the date of the transaction recorded. Records of controlled substances lost, destroyed or stolen, shall contain a detailed list of the kind and quantity of such drugs and the date of discovery of such loss, destruction or theft. Iowa Code section 124.306.

The Board’s rules governing controlled substance record keeping are found at 657 IAC 10.34. The rules are consistent with Iowa Code section 124.306 but further provide that records must be kept by the registrant and available for inspection or copying by the board or its representative for at least two years from the date of such inventory or record except as otherwise required in these rules.¹⁰ Controlled substance records shall be maintained in *readily retrievable manner* that establish the receipt and distribution of controlled substances. Original hard-copy prescription and other pharmacy records more than 12 months old may be maintained in a *secure storage area* outside the licensed pharmacy department, but the remote storage area shall be located within the same physical structure containing the licensed pharmacy department. 657 IAC 10.34 (emphasis added). 657 IAC 8.9 includes these same requirements.

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated Iowa Code section 124.306 and 657 IAC 10.34 by failing to create and maintain required documentation of the pharmacy’s invoices for the purchase of hydrocodone and for failure to maintain annual inventories of its hydrocodone products. Respondents failed to ensure that invoices were properly signed and dated and failed to maintain controlled substances invoices and inventories in a readily retrievable manner. In addition, many records, including confidential prescription records, were stored in the pharmacy’s basement, which was not secure.

¹⁰ As discussed at hearing, Schedule II-V controlled substance prescriptions are valid for six months and may be authorized for up to five refills. See 657 IAC 10.28. Records of controlled substance prescriptions must be kept for two years from the last refill date.

***Count IV: Bauder Pharmacy and Mark Graziano
Failure to Properly Sign and Date Invoices for Controlled Substances***

657 IAC 8.9(1) requires all pharmacies to maintain supplier invoices of prescription drugs and controlled substances upon which the actual date of receipt of the controlled substances by the pharmacist or other responsible individual is clearly recorded. The invoices must be maintained for at least two years.

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 8.9(1) by not maintaining all supplier invoices for a period of two years and by not ensuring that a pharmacist or other responsible individual signed the invoice to clearly record receipt of the controlled substances listed on the invoice.

***Count V: Bauder Pharmacy and Mark Graziano
Dispensing Schedule II Controlled Substances in Quantities Exceeding Prescriber
Authorization***

657 IAC 10.21(5) authorizes a pharmacist, after consultation with the prescriber or the prescriber's agent and documentation of such consultation, to change the drug strength, dosage form, or drug quantity on a Schedule II controlled substance prescription. During the March 16, 2012 pharmacy inspection, Jean Rhodes found a prescription for oxycontin 20mg/ml that was written for 10 ml. The manufacturer supplied the drug as a 30ml container and this is what the pharmacy dispensed, but there was no documentation that the prescriber authorized the change. Following the inspection, Mark Graziano corrected this deficiency by obtaining a corrected prescription from the prescriber. The Board concluded that this corrected deficiency involving one prescription does not merit finding a separate violation against Respondents.

***Count VI: Bauder Pharmacy and Mark Graziano
Failure to Comply with Requirements for Partial Filling***

657 IAC 10.23 is the Board's rule regulating partial filling of Schedule II controlled substances. If a pharmacy is unable to supply the full quantity called for in a prescription, the pharmacists may partially fill a prescription, so long as the pharmacist notes the quantity provided on the prescription record and the

remaining portion of the prescription is filled within 72 hours of the first partial filling. No further quantity may be supplied beyond 72 hours without a new prescription.

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 10.23 when they partially filled Schedule II prescriptions and then filled the balance of the prescription more than 72 hours after the partial filling. This deficiency was specifically cited at the time of the March 16, 2012 inspection.

***Count VII: Bauder Pharmacy and Mark Graziano
Failure to Maintain Complete and Accurate Perpetual Inventories of Schedule II
Controlled Substances***

657 IAC 10.33 requires all pharmacies that dispense Schedule II controlled substances to maintain a perpetual inventory system for all Schedule II controlled substances in accordance with the rule. The perpetual inventory must be available for inspection and copying by the board or its representative for a period of two years from the date of the record.

The perpetual inventory may be maintained in a manual or electronic format. 657 IAC 10.33(1). The perpetual inventory record shall identify all receipts for and disbursements of Schedule II controlled substances by drug or by nation drug code (NDC) number. The record shall be updated to identify each prescription filled and each shipment received. 657 IAC 10.33(2). The pharmacist in charge shall be responsible for reconciling the physical inventory of all Schedule II controlled substances with the perpetual inventory balance on a periodic basis but no less frequently than annually. In case of any discrepancies between the physical inventory and the perpetual inventory, the pharmacist in charge shall determine the need for further investigation, and significant discrepancies shall be reported to the board pursuant to rule 10.16(124) and to the DEA pursuant to DEA regulations. 657 IAC 10.33(4).

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 10.33 when they failed to maintain a complete and accurate perpetual inventory of Schedule II controlled substances. At the time of the March 16, 2012 inspection, the perpetual inventory for Schedule II controlled substances had multiple negative balances due to errors in the way the pharmacy was partially filling Schedule II controlled substances. When a Schedule II

prescription was partially filled, the actual amount dispensed should have been recorded. When the pharmacy dispensed the owed quantity on the prescription, there should have been a separate entry.

***Count VIII: Bauder Pharmacy and Mark Graziano
Failure to Maintain Complete and Accurate Inventory of Controlled Substances***

All registrants are required to take an initial inventory of all stocks of controlled substances on hand on the date the registrant commences business and is thereafter required to take a new inventory of all stocks of controlled substances on hand at least annually. The annual inventory may be taken on any date that is within one year of the previous inventory date. 657 IAC 10.35(2),(3). Each inventory record must comply with the requirements of subrule 10.35 and must be maintained for a minimum of two years from the date of the inventory. 657 IAC 10.35(1). Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date and at the time the inventory is taken. 657 IAC 10.35(1)(a).

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 10.35 when they failed to maintain complete and accurate inventories of the Schedule III controlled substances. Respondents clearly were not maintaining accurate inventories when many hundreds of thousands of hydrocodone were missing from the pharmacy.

***Count IX: Bauder Pharmacy and Mark Graziano
Failure to Document Verification of Controlled Substance Refills***

657 IAC 21.5 requires the individual pharmacist who makes use of the pharmacy prescription application to provide documentation of the fact that the refill information entered into the pharmacy prescription application each time the pharmacist refills an original written, fax, or oral prescription order for a controlled substance is correct.

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 21.5 when they failed to document verification of controlled substance refills for a period of two years. This deficiency was noted during the March 16, 2012 inspection and was cited in the March 22, 2012 inspection report. Mark Graziano admitted to Jean Rhodes that he did not

understand this requirement. He believed that his reports to the PMP provided sufficient documentation of verification.

***Count X: Bauder Pharmacy and Mark Graziano
Failure to Properly Supervise Dispensing Functions Delegated to Non-
Pharmacists***

This count cites 657 IAC 3.20, which states that the ultimate responsibility for the actions of a pharmacy technician shall remain with the supervising pharmacist. The Board was unable to find any evidence to support a separate violation under this count. The pharmacy and pharmacist in charge were responsible for the pharmacy technician's failure to have a current registration for more than two years, but this violation is addressed in Count XII.

***Count XI: Bauder Pharmacy and Mark Graziano
Failure to Maintain Complete Patient Records***

657 IAC 6.13(1) specifies the patient record system that must be maintained by all pharmacies. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist shall be responsible for obtaining, recording, and maintaining the following information: *a.* known allergies;...*g.* [p]harmacist comments relevant to the individual's drug therapy, including (1) known drug reactions, ...(3) [k]nown chronic disease conditions or disease states of patients, (4) [t]he identity of other drugs, over-the-counter drugs, herbals, other alternative medications, ...that may relate to prospective drug review.

This count relates to the two shopper survey reports. One shopper reported that she was not asked for any patient history, current health conditions, medications or allergies when her new prescription was filled by Mark Graziano. The second shopper reported that she was asked about allergies but was not asked about disease states or other medications that she was taking. The shoppers did not testify at hearing and the record does not include the pharmacy's patient records for the two shoppers. The Board declined to find separate violations with respect to this count.

***Count XII: Bauder Pharmacy and Mark Graziano
Failure to Ensure All Pharmacy Technicians Have Current Registration***

657 IAC 3.11(2) provides that a pharmacy technician registration that is not renewed before its expiration date shall be delinquent, and the registrant shall not continue employment as a pharmacy technician until the registration is reactivated. An individual who continues employment as a pharmacy technician without a current registration, in addition to the pharmacy and the pharmacist in charge that allow the individual to continue to practice as a pharmacy technician, may be subject to disciplinary sanctions. See also 657 IAC 36.1(4)(aa).

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 3.11(2) and 36.1(4)(aa) when they permitted Jennifer Higgins to continue working as a pharmacy technician for nearly eighteen months after her pharmacy technician registration had expired.

***Count XIII: Bauder Pharmacy and Mark Graziano
Failure to Maintain Policies and Procedures for the Operation of the Pharmacy***

657 IAC 6.2(14) provides that there must be one professionally competent, legally qualified pharmacist in charge of each pharmacy who is responsible for establishing and implementing policies and procedures for all operations of the pharmacy. The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 6.2(14) by failing to have adequate written policies and procedures for all operations of the pharmacy. It is the responsibility of the pharmacist in charge to establish and implement policies and procedures for all operations of the pharmacy. The March 22, 2012 inspection report and the credible testimony of Jean Rhodes establishes that there were only minimal policies and procedures for Bauder Pharmacy, mostly relating to interns, at the time of the March 16th inspection. The pharmacy did not even have interns at the time of the inspection. In addition, when Ms. Rhodes returned to Bauder Pharmacy on October 11, 2012, pharmacist in charge Kim Robertson was unable to provide the policies and procedures for the operation of the pharmacy.

***Count XIV: Bauder Pharmacy and Mark Graziano
Failure to Provide Proper Security for Prescription Medications and Pharmacy
Records Stored in Basement***

657 IAC 6.7 provides that while on duty, each pharmacist shall be responsible for the security of the prescription department, including provisions for the effective control against theft of, diversion of, or unauthorized access to prescription drugs, records for such drugs, and patient records as provided in 657-Chapter 21. The prescription department shall be locked by key or combination so as to prevent access when a pharmacist is not on site, except as provided in subrule 6.7(2). The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 6.7 when they stored prescription medications and confidential patient records in the pharmacy's basement, which was unlocked and not protected from unauthorized access.

***Count XV: Mark Graziano
Failure to Wear an Identification Badge***

657 IAC 8.4(4) requires pharmacists to wear a visible identification badge while on duty that clearly identifies the person as a pharmacist and includes at least the pharmacist's first name. The preponderance of the evidence established that Mark Graziano violated 657 IAC 8.4(4) when he repeatedly failed to wear an identification badge while working in the pharmacy.

***Count XV: Bauder Pharmacy and Count XVI: Mark Graziano
Failure to Have Required Policies, Procedures and Documentation for Pharmacy
Technician Training***

657 IAC 8.14 requires all Iowa-licensed pharmacies utilizing pharmacy technicians or pharmacy support persons to develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy technicians and pharmacy support persons appropriate to the practice of pharmacy at that licensed location. Pharmacy policies shall specify the frequency of review. Pharmacy technician and support person training shall be documented and maintained by the pharmacy for the duration of employment. Policies and procedures and documentation of pharmacy technician and pharmacy support person training shall be available for inspection by the board or an agent of the board.

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 8.14 when they failed to establish policies and procedures for the training and utilization of pharmacy technicians and failed to document pharmacy technician and support person training. This deficiency was documented in the March 22, 2012 inspection report and the credible testimony of Jean Rhodes. In addition, when Jean Rhodes returned to the pharmacy on October 11, 2012 to review the deficiency corrections with then pharmacist in charge Kim Robertson, the pharmacy still did not have a technician training policy.

***Count XVI: Bauder Pharmacy and Count XVII: Mark Graziano
Failure to Have a Continuous Quality Improvement Program***

657 IAC 8.26 requires all licensed pharmacies to implement and participate in a continuous quality improvement program or CQI program. The CQI program is intended to be an ongoing, systematic program of standards and procedures to detect, identify, evaluate, and prevent medication errors, thereby improving medication therapy and quality of patient care.

The pharmacist in charge is responsible for ensuring that the pharmacy utilizes a CQI program consistent with the requirements of the rule.¹¹ Each pharmacy shall develop, implement, and adhere to written policies and procedures for the operation and management of the pharmacy CQI program. A copy of the pharmacy's CQI program description and policies and procedures shall be maintained and readily available to all pharmacy personnel.¹²

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 8.26 by failing to have a written CQI program. This deficiency was documented in the March 22, 2012 inspection report and the credible testimony of Jean Rhodes. In addition, when Jean Rhodes returned to the pharmacy on October 11, 2012 to review the deficiency corrections with then pharmacist in charge Kim Robertson, the pharmacy still did not have a technician training policy.

¹¹ 657 IAC 8.26(2).

¹² 657 IAC 8.26(3).

***Count XVII: Bauder Pharmacy and Count XVIII: Mark Graziano
Failure to Meet Minimum Standards for Sterile Compounding***

“Sterile compounding” means the aseptic processing in a clean environment of any pharmaceutical preparations that are required to be sterile when they are administered into patient body cavities, central nervous and vascular systems, eyes and joints,..., including but not limited to injections (e.g., colloidal dispersions, emulsions, solutions, and suspensions)...¹³ 657 IAC Chapter 13 is entitled *“Sterile Compounding Practices”* and establishes the standards and procedures for the preparation, labeling, and distribution of sterile preparations by licensed pharmacies pursuant to a practitioner’s order or prescription.¹⁴

657 IAC 13.3(1) provides that each pharmacy shall have a pharmacist responsible for ensuring that:

- a. Preparations are accurately identified, measured, diluted, and mixed; and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed.
- b. Appropriate cleanliness conditions are maintained, including preservation of the sterile environment during the compounding process.
- c. Beyond-use dates are established based on direct testing or extrapolation from reliable literature sources. The pharmacy shall maintain written justification of the chosen beyond-use date or, if a written standard is not available, a maximum 24-hour expiration shall be used.
- d. Equipment, apparatus, and devices used to compound a preparation are consistently capable of operating properly and within acceptable tolerance limits.

Each pharmacy that performs sterile compounding is also required to have a written quality assurance procedure.¹⁵

657 IAC 13.3(3) provides that all personnel involved with compounding, repackaging, or manipulating sterile preparations shall be adequately educated

¹³ 657 IAC 13.2.

¹⁴ 657 IAC 13.1.

¹⁵ 657 IAC 13.3(2).

and trained. Training shall include written documentation certifying that the compounding personnel are able to adequately complete the activities listed in subsections "a" to "f."

657 IAC 13.6 requires pharmacies performing sterile compounding to have a written policy and procedure manual for the compounding, dispensing, delivery, administration, storage, and use of sterile preparations. The manual shall establish policies and procedures relating to subjects identified in this rule and other rules within 657 IAC chapter 13.

657 IAC 13.31 requires pharmacies to establish, implement, and document an ongoing quality assurance program in order to maintain and improve facilities, equipment, personnel performance, and the provision of patient care.

Mark Graziano was the only pharmacist performing sterile compounding at Bauder Pharmacy. Mr. Graziano was responsible for developing all required policies and procedures for sterile compounding, including the development of a written quality assurance procedure. Mr. Graziano was also responsible for documenting that he was adequately educated and trained. The preponderance of the evidence established that Respondents Bauder Pharmacy and Mark Graziano violated 657 IAC 13.3, 13.3(2), 13.6, and 13.31 by failing to develop and implement written policies and procedures for sterile compounding, including failure to adopt a written quality assurance program. Bauder Pharmacy and Mark Graziano violated 657 IAC 13.3(3) by failing to document appropriate education, training, and proficiency of the pharmacy's compounding personnel.

657 IAC 13.7(2) relates to batch preparation and requires each container of a batch preparation compounded in anticipation of later dispensing to bear a label with at least the following information: name and quantity of all contents, internal code to identify the date and time of preparation and the preparer's and reviewing pharmacist's initials or unique identifiers, stability (beyond-use date) as set forth in the pharmacy's policy and procedure manual, and auxiliary labels as needed.

The preponderance of the evidence established that at the time of the March 16, 2012 pharmacy inspection, the refrigerator in the sterile compounding area of Bauder Pharmacy had two unlabeled vials of HCG injectable, and there were no batch records for the product, in violation of 657 IAC 13.7(2).

657 IAC 13.11 establishes maximum storage periods for low-risk preparations. In the absence of the preparation passing a sterility test and provided the preparation is properly stored before administration, the storage periods shall not exceed 14 days at a cold temperature. 657 IAC 13.11(1)"d"(2).

The preponderance of the evidence established that Mark Graziano had assigned a 30 day beyond-use date to Lupron injections that were only permitted to have a 14 day beyond-use date.

657 IAC 13.25 requires the pharmacy to develop, maintain, and implement written procedures that include appropriate media-fill testing (MFT) by personnel authorized to compound preparations. Each person authorized to compound low-risk preparation shall annually perform a successful MFT procedure. 657 IAC 13.25(1).

The preponderance of the evidence established that Mark Graziano had never performed media-fill testing, in violation of 657 IAC 13.25. Mr. Graziano ordered a kit that was to be delivered in May 2012, but the pharmacy ceased performing sterile compounding after Mr. Graziano's pharmacist license was suspended, effective May 10, 2012.

657 IAC 13.27 requires, in part, that the primary engineering control device was to be placed in a buffer area with cleanable, nonshedding, smooth surfaces; all junctures shall be covered; and all cracks and crevices shall be caulked. 657 IAC 13.28 requires the pharmacy to have appropriate equipment and supplies and documented procedures for maintaining an environment suitable for the aseptic processing of sterile preparations.

The preponderance of the evidence established that several junctures in the buffer area needed recaulking and that peeling paint needed to be repaired, in violation of 657 IAC 13.27. The preponderance of the evidence further established that the pharmacy did not have written cleaning procedures or any documentation of cleaning, in violation of 657 IAC 13.28. Jean Rhodes was able to verify that these particular deficiencies had been corrected as of April 12, 2012.

657 IAC 13.29(1) requires all cleanrooms, laminar airflow workbenches, and barrier isolators to be certified by an independent contractor according to ISO Standards at least every six months. 657 IAC 13.29(2) requires the pharmacy to establish written procedures, appropriate to the risk level preparations

compounded by the pharmacy, which must include environmental testing, end testing, and evaluation of validation results. 657 IAC 13.29(2)(a) and (b) requires pharmacies to perform microbial air sampling and pressure differential monitoring.

The preponderance of the evidence established that Bauder Pharmacy only obtained certification of its clean rooms yearly, rather than every six months, in violation of the requirements of 657 IAC 13.29(1). The March 22, 2012 Inspection Report was the second notice on this violation. In addition, Bauder Pharmacy had never performed microbial sampling, had no pressure differential monitors, and had no procedures concerning environmental requirements. These deficiencies were not corrected by the pharmacy within 30 days.

***Count XVIII: Bauder Pharmacy and Count XIX: Mark Graziano
Failure to Provide Labeling and Record Keeping for Med Paks***

In lieu of dispensing prescribed drug products in conventional prescription containers, a pharmacist may, with the consent of the patient, the patient's caregiver, or the prescriber, provide a customized medication package (patient med pak) pursuant to the requirements of 657 IAC 22.5. A patient med pak is a customized patient medication package prepared for a specific patient which comprises a series of immediate containers containing prescribed solid oral dosage forms, each container being labeled with the time or the appropriate period for the patient to take its contents.¹⁶

The patient med pak shall be labeled as provided by 657 IAC 22.5(5), with the patient's name; a unique identification number for the patient and med pak and a separate identification number for each of the prescription drug orders for each of the drug products contained in the med-pak; the name, strength, dosage form, and total quantity of the drug; directions for use of each drug product; name of prescriber for each drug product; the date of preparation of the patient med-pak and the assigned beyond-use date; the name, address, and telephone number of the pharmacy; and the initials or unique identification of the responsible pharmacist.¹⁷ Pharmacies are also required to keep records of all med-paks.¹⁸

¹⁶ 657 IAC 22.5(1).

¹⁷ 657 IAC 22.5(5).

¹⁸ *Id.*

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 22.5 by failing to provide labeling and recordkeeping for the medpaks that it prepared for four customers.

***Count XIX: Bauder Pharmacy and Count XX: Mark Graziano
Failure to Provide Adequate Patient Counseling***

Patient counseling is required by Board rule.¹⁹ Pharmacists and pharmacies may be disciplined for attempting to circumvent patient counseling requirements or discouraging patients from receiving patient counseling concerning their prescription drug orders.²⁰ These counts were based on the shopper survey reports. Although the patient counseling reported by the two shoppers appeared to fall below Board expectations, the Board concluded that there was insufficient evidence to support separate findings of violation on these counts.

***Count XX: Bauder Pharmacy
Failing to Report Change in Pharmacist in Charge and Failing to Comply With
Requirements for Making the Change***

Iowa Code section 155A.19(1)(d) requires pharmacies to report to the Board, in writing, any change in the pharmacist in charge. 657 IAC 8.35(6)(c) requires a pharmacy to notify the Board, in writing, of a temporary pharmacist in charge within 10 days following a vacancy in the pharmacist in charge position. A permanent pharmacist in charge shall be identified within 90 days following the vacancy.

Effective May 10, 2012, the Board suspended the pharmacist license of Mark Graziano, who was the pharmacist in charge of Bauder Pharmacy. During a visit to the pharmacy on June 20, 2012, Compliance Officer Jean Rhodes had reminded Kim Robertson, R.Ph. that the pharmacy still had not identified a pharmacist in charge. The preponderance of the evidence established that Bauder Pharmacy violated Iowa Code section 155A.19(1)(d) and 657 8.35(6)(c) when it waited until July 23, 2012 to notify the Board that Kim Robertson was the new pharmacist in charge.

¹⁹ See 657 IAC 6.14.

²⁰ 657 IAC 36.1(4)(w).

***Count XXI: Mark Graziano
Failing to Meet the Requirements for Practicing as Pharmacist in Charge***

657 IAC 6.2 provides, in relevant part:

657-6.2(155A) Pharmacist in charge. One professionally competent, legally qualified pharmacist in charge in each pharmacy shall be responsible for, at a minimum, the following:

...

6. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.

7. Delivering drugs to the patient or the patient's agent.

...

9. Training pharmacy technicians and pharmacy support persons.

10. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.

11. Distributing and disposing of drugs from the pharmacy.

12. Maintaining records of transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations.

13. Establishing and maintaining effective controls against the theft or diversion of prescription drugs and records for such drugs.

14. Establishing and implementing policies and procedures for all operations of the pharmacy.

15. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.

16. Ensuring that there is adequate space within the prescription department or a locked room not accessible to the public for the storage of prescription drugs, devices and controlled substances and to support the operations of the pharmacy.

The preponderance of the evidence established that Mark Graziano's performance as pharmacist in charge of Bauder Pharmacy was completely inadequate and failed to properly fulfill the above-listed responsibilities of the pharmacist in charge, in violation of 657 IAC 6.2.

***Count XXI: Bauder Pharmacy and Count XXII: Mark Graziano
Failing to Comply with Board Rules Regarding Manner of Issuance of
Prescription Drug or Medication Order***

657 IAC 8.19 specifies the manner of issuance of a prescription drug or medication order. A prescription drug order or medication order may be transmitted from a prescriber or a prescriber's agent to a pharmacy in written form, orally including telephone voice communication, by facsimile transmission as provided in 657-21.9, or by electronic transmission in accordance with applicable federal and state laws, rules and regulations. Any prescription drug order provided to a patient in written or printed form shall include the original, handwritten signature of the prescriber except as provided in 657-21.7.

A written, electronic, or facsimile prescription shall include: the date issued, the name and address of the patient, the name, strength, and quantity of the drug or device prescribed, the name and address of the prescriber and, if the prescription is for a controlled substance, the prescriber's DEA registration number, and the written or electronic signature of the prescriber.²¹

A prescription transmitted via facsimile shall include the identification number of the facsimile machine used to transmit the prescription to the pharmacy, the time and date of transmission, the name, address, telephone number and facsimile number of the pharmacy to which the prescription is being transmitted, and the manual signature of the prescriber if the prescription is for a controlled substance.²²

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano repeatedly violated 657 IAC 8.19. A review of 614 randomly selected prescriptions that were filled by the pharmacy between 2008 and 2012 revealed that only 166 of the prescriptions were legally correct. The remaining 448 prescriptions were incorrect or incomplete in one of the following respects:

- Sender's information cut off from fax;
- Wrong patient;
- Wrong prescriber;

²¹ 657 IAC 8.19(1)(a).

²² 657 IAC 8.19(1)(c).

- Wrong medication;
- No prescriber signature or verification;
- Wrong number of refills;
- Wrong directions;
- No prescriber DEA number for controlled substances;
- Faxed prescription not signed by prescriber;
- Wrong dispensed quantity;
- Filled beyond authorized time period;
- Filled prior to authorization;
- RX denied by prescriber but filled by pharmacy;
- No prescribed quantity;
- RX number not recorded on prescription;
- Dispensed generic when prescription indicated "Do not substitute."

***Count XXII: Bauder Pharmacy and Count XXIII: Mark Graziano
Failing to Comply with Board Rule Regarding Controlled Substance
Prescription Requirements***

657 IAC 10.21 provides that all prescriptions for controlled substances shall be dated as of, and signed on the date issued. Controlled substances prescriptions shall be valid for six months following the date of issue. A prescription for Schedule II, IV or V controlled substance may include authorization to refill the prescription no more than five times within the six months following date of issue. A prescription for a Schedule II controlled substance shall not be refilled.

657 IAC 10.21(1) *Form of prescription.* All prescriptions shall bear the full name and address of the patient; the drug name, strength, dosage form, quantity prescribed and directions for use; and the name, address, and DEA registration number of the prescriber...A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by this rule.

Androgel is an anabolic steroid that has also been placed in Schedule III.²³ The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano repeatedly violated 657 IAC 10.21 when Androgel was dispensed by the pharmacy without obtaining a legally correct prescription from a prescriber. The Androgel prescriptions reviewed by the Board's compliance officers including the following deficiencies:

²³ Iowa Code section 124.208(6)(be).

- No Dr. DEA number;
- No hardcopy in file;
- No prescriber signature;
- Stamped prescriber signature;
- Unauthorized refills dispensed;
- Refilled beyond 6 months;
- Initial file after prescription had expired (6 months);
- No patient name on hard copy prescription;
- No notation of verbal authorization;
- No RX number on prescription;
- Sender information cut off from fax;
- Wrong dosage form of medication;
- Filled prior to receipt of fax authorization.

***Count XXIII: Bauder Pharmacy and Count XXIV
Failing to Comply with Board Rules Regarding Faxed Prescriptions***

657 IAC 21.9 permits a pharmacist to dispense noncontrolled and controlled drugs, excluding Schedule II controlled substances, pursuant to a prescription faxed to the pharmacy by the prescribing practitioner or the practitioner's agent. The faxed prescription drug order shall serve as the original prescription, shall be maintained for a minimum of two years from the date of last fill or refill, and shall contain all information required by Iowa Code section 155A.27, including the prescriber's signature or electronic signature. The faxed prescription drug order, if transmitted by the practitioner's agent, shall identify the transmitting agent by first and last names and title and shall include the prescriber's signature or electronic signature. A prescription for a controlled substance shall include the prescriber's manual signature. 657 IAC 21.3 addresses the pharmacist's responsibility to verify the authenticity of an electronically prepared or electronically or fax transmitted prescription.

The Board believes that Respondents' violations with respect to deficiencies in its faxed prescriptions have been adequately addressed under the prior two counts (Counts XXII and XXIII for Bauder Pharmacy and Counts XXIII and XXIV for Mark Graziano). The Board believes it is unnecessary to find additional violations under these counts.

***Count XXIV: Bauder Pharmacy and Count XXV: Mark Graziano
Failing to Comply with Board Rules Regarding Prescription Processing
Documentation***

657 IAC 6.8 requires all prescriptions to be dated and assigned a unique identification number that shall be recorded on the original prescription. The original prescription, whether transmitted orally, electronically, or in writing, shall be retained by the pharmacy. Refill documentation shall include date of refill and the initials or other unique identification of the pharmacist. Upon review of the record, the Board believes that the pharmacy had the required logs, although they were not signed by a pharmacist. The Board declines to find additional violations under these counts.

***Count XXV: Bauder Pharmacy and Count XXVI: Mark Graziano
Failing to Comply with Board Rules Regarding Record Retention Requirements***

657 IAC 8.9 provides that each inventory or other record required to be maintained by a pharmacy pursuant to board rules or Iowa Code chapters 124 and 155A shall be maintained and be available for inspection and copying by the board or its representative for at least two years from the date of such inventory or record unless a longer retention period is specified for the particular record or inventory. Original hard copy prescription and other pharmacy records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department unless such remote storage is prohibited under federal law. A remote storage area shall be located within the same physical structure containing the licensed pharmacy department. The following records shall be maintained for at least two years.

8.9(1) Drug supplier invoices. All pharmacies shall maintain supplier invoices of prescription drugs and controlled substances upon which the actual date of receipt of the controlled substances by the pharmacist or other responsible individual is clearly recorded.

...

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 8.9 by failing to retain all drug supplier invoices for a minimum period of two years and by failing to record the date of receipt of controlled substances on all of the invoices.

***Count XXVI: Bauder Pharmacy and Count XXVII: Mark Graziano
Dispensing Controlled Substances Without a Prescription***

Iowa Code section 124.308(4) provides that except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance in Schedule III or IV, which is a prescription drug as determined under chapter 155A, shall not be dispensed without a written or oral prescription of a practitioner or without an electronic or facsimile prescription in accordance with subsection 5.

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated Iowa Code section 124.308(4) by the repeated dispensing of large numbers hydrocodone tablets without a proper prescription. The factual basis for this violation was fully discussed in connection with Count I. In addition, Respondents violated Iowa Code section 124.308(4) when AndroGel was repeatedly dispensed without a valid prescription. The Board declined to find a violation under this count with respect to the prescriptions filled at Bauder Pharmacy for CG.

Sanctions

The Board may consider the following factors in determining the nature and severity of disciplinary sanctions: the relative seriousness of the violation as it relates to assuring citizens of this state a high standard of professional care, the facts of the particular violation, any extenuating circumstances or other countervailing considerations, the number of prior violations or complaints, seriousness of prior violations or complaints, whether remedial action has been taken, and any other factors as may reflect upon the competency, ethical standards, and professional conduct of the licensee, registrant, or permittee.²⁴

The record includes a table summarizing prior cases where the Board has disciplined pharmacies and/or pharmacists for illegal diversion of or failure to properly account for controlled substances. (State Exhibit 77). The table provides minimal information about the particular facts of those cases. It is, however, abundantly clear to the Board that the violations in this case are far more egregious than these prior cases. This case involves far larger numbers of missing hydrocodone tablets as well as compelling evidence that the pharmacist in charge, who is also the majority owner of the pharmacy, was directly involved

²⁴ 657 IAC 36.1(3).

in the illegal distribution of the drugs. The violations established in this Decision and Order seriously threatened the public health, safety, and welfare.

In addition, a number of Respondents' other violations, including but not limited to the violations involving sterile compounding, also raise grave concerns for public health and safety. The Board's findings of violation in this case more than justify imposing the most severe disciplinary sanctions available to the Board, including permanent revocation of Mark Graziano's license to practice pharmacy and revocation of Bauder Pharmacy's controlled substance registration.

With respect to the pharmacy's controlled substance registration, it is true, as pointed out by the state, that the Order of Immediate Suspension and Order to Show Cause stated: **IF YOU DESIRE A HEARING REGARDING SUSPENSION AND POSSIBLE REVOCATION OF THIS CONTROLLED SUBSTANCE REGISTRATION, YOU MUST FILE A REQUEST FOR A HEARING BEFORE THE BOARD WITHIN THIRTY (30) DAYS OF ISSUANCE OF THIS ORDER...IF RESPONDENT DOES NOT REQUEST HEARING IN THIS MATTER WITHIN THIRTY DAYS OF THE DATE OF THIS ORDER, RESPONDENT'S CONTROLLED SUBSTANCE REGISTRATION WILL BE DEEMED REVOKED WITHOUT FURTHER ORDER OF THE BOARD.** (Emphasis original)

In its brief filed on the day of the hearing, the state asserted that Bauder Pharmacy's controlled substances registration has already been "deemed revoked" because Bauder Pharmacy did not file a request for hearing on the immediate suspension of its controlled substances registration. Respondent's counsel did not specifically respond to this argument at hearing.

A review of the Board's legal file does not reveal any specific written request from Bauder Pharmacy for a hearing on the issue of the immediate suspension of its controlled substances registration. Nevertheless, the Board notes that the initial Order Granting Motion for Continuance, which was issued by the Board on May 15, 2012, states:

On May 11, 2012, the Respondents, Bauder Pharmacy, Inc. and Mark E. Graziano, through attorneys Mark Weinhardt and George LaMarca, requested a continuance of the hearing on the statement of charges, emergency order, and order of immediate suspension and order to show cause against the Respondents, Bauder

Pharmacy, Inc. and Mark E. Graziano. Respondents have provided sufficient justification for its motion for continuance.

This continuance order could be interpreted as the Board's acknowledgement that Bauder Pharmacy, Inc. did request a hearing on the Order for Immediate Suspension and Order to Show Cause. For this reason, the Board has elected to consider and address the issue of Respondent's controlled substance registration in this Decision and Order, rather than "deeming" the controlled substance registration to have been revoked.

DECISION AND ORDER

IT IS THEREFORE ORDERED that pharmacist license number 16752, issued to Mark Graziano, is hereby PERMANENTLY REVOKED.

IT IS FURTHER ORDERED that controlled substance registration number 1100280, issued to Bauder Pharmacy, Inc., is hereby REVOKED.

IT IS FURTHER ORDERED that pharmacy license number 222, issued to Bauder Pharmacy, Inc., is hereby issued a CITATION and WARNING for the violations of Board statutes and rules established in this Decision and Order.

IT IS FURTHER ORDERED that pharmacy license number 222, issued to Bauder Pharmacy, Inc., is hereby placed on INDEFINITE PROBATION, subject to the following terms and conditions:

A. Respondent Bauder Pharmacy, Inc. shall pay a civil penalty in the amount of \$25,000. The civil penalty payment shall be made by check, payable to the Treasurer of Iowa and mailed to the executive director of the Board within thirty (30) days of the issuance of this Decision and Order. All civil penalty payments shall be deposited into the State of Iowa general fund.

B. Within thirty (30) days of the issuance of this Decision and Order, Respondent Bauder Pharmacy, Inc. shall submit, for Board approval, a written plan of action for correcting all remaining deficiencies identified in this Decision and Order.

C. Respondent Bauder Pharmacy, Inc. is hereby prohibited from performing any sterile compounding, unless otherwise ordered by the Board. The pharmacy shall not request permission to resume sterile compounding until such time as the pharmacist in charge can verify proper training of staff and the adoption of policies and procedures for sterile compounding in accordance with Board rules and approved by the Board.

D. Within thirty (30) days of the issuance of this Decision and Order, Respondent Bauder Pharmacy, Inc. shall submit, for Board approval, policies and procedures for all operations of the pharmacy.

E. Within thirty (30) days of the issuance of this Decision and Order, Respondent Bauder Pharmacy, Inc. shall submit, for Board approval, a Quality Control Improvement (CQI) plan.

F. Respondent Bauder Pharmacy, Inc. shall obtain Board approval for every pharmacist in charge of the pharmacy.

G. Mark Graziano shall be allowed no access to the pharmacy department or to prescription drugs within the pharmacy.

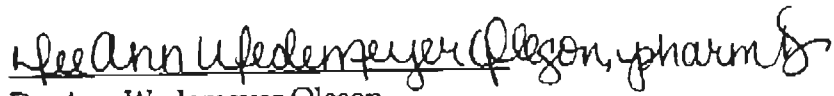
H. There shall be quarterly inspections of Bauder Pharmacy, Inc. to ensure full compliance with the rules governing pharmacy practice. Such inspections shall be conducted by a consultant approved by the Board, and shall be at the pharmacy's expense. The pharmacy shall comply with all recommendations made by the consultant. The pharmacy and the consultant shall submit quarterly reports to the Board. The reports shall be filed not later than March 5, June, 5, September 5, and December 5 of each year of the indefinite probation.

IT IS FURTHER ORDERED, pursuant to Iowa Code section 272C.6 and 657 IAC 36.18(2), that Respondents Mark Graziano and Bauder Pharmacy shall pay \$75.00 for fees associated with conducting the disciplinary hearing. In addition, the executive secretary/director of the Board may bill Respondent for any witness fees and expenses or transcript costs associated with this disciplinary hearing. Respondent shall remit for these expenses within thirty (30) days of receipt of the bill.

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Dated this 5th day of April, 2013

A handwritten signature in cursive script that reads "DeeAnn Wedemeyer Oleson, PharmD". The signature is written in dark ink and is positioned above the printed name.

DeeAnn Wedemeyer Oleson

Vice-Chairperson

Iowa Board of Pharmacy

cc: Theresa O'Connell Weeg, Assistant Attorney General
Rick Olson, Respondent's Attorney

Any aggrieved or adversely affected party may seek judicial review of this decision and order of the board, pursuant to Iowa Code section 17A.19.